APPENDIX P

SURVEY PROTOCOL FOR LONG TERM CARE FACILITIES

PART I

Survey Procedures for Long Term Care Facilities

Part II

Guidance to Surveyors - Long Term Care Facilities

Column I	Tag Number
Column II	Regulation
Column III	Guidance to Surveyors (Guidelines and Survey Procedures and Probes)

I. INTRODUCTION

Skilled nursing facilities (SNFs) and nursing facilities (NFs) are required to be in compliance with the requirements in 42 CFR Part 483, Subpart B, to receive payment under the Medicare or Medicaid programs. To certify a SNF or NF, complete at least a:

- o Life Safety Code (LSC) survey, and

- o Standard Survey, (Forms HCFA-670, 671, 672, 677, and 801 through 807). (See Exhibits 85, 86, and 88 to 95.)

Do not announce SNF/NF surveys to the facility. Conduct standard surveys and complete them on consecutive workdays, whenever possible. They may, at your discretion, be conducted at any time including weekends, 24 hours a day. When standard surveys begin at times beyond the business hours of 8:00 a.m. to 6:00 p.m., or begin on a Saturday or Sunday, the entrance conference and initial tour should be modified in recognition of the residents' activity (e.g., sleep, religious services) and types and numbers of staff available upon entry.

Use the standard survey procedure discussed in this section for all standard surveys of SNFs and NFs, whether freestanding, distinct parts, or dually participating. For surveys of facilities predominantly serving short stay residents, modifications of offsite survey preparation and sampling procedures will be necessary.

NOTE: Do not use this process for surveys of intermediate care facilities for the mentally retarded (ICFs/MR), swing-bed hospitals, or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Survey Protocols and Interpretive Guidelines for these surveys are found in Appendices J (ICFs/MR) and T (Swing-bed hospitals and hospitals with non-distinct part SNFs).

When the surveyor team suspects substandard quality of care (SQC), expand the standard (or abbreviated) survey sample as necessary to determine scope. (See Task 4, Supplementary Sample, for further information). If, at Task 6, the existence of SQC is verified, then inform the administrator that the facility is in SQC and an extended (or partial extended) survey will be conducted.

A. Surveys.--If in conducting the information gathering tasks of the survey you identify a possible noncompliant situation related to any requirement, investigate the situation to determine whether the facility is in compliance with the requirements.

1. Standard Survey.--A standard survey is composed of Tasks 1 - 7, and is a resident-centered, outcome-oriented inspection which relies on a case-mix stratified sample of residents to gather information about the facility's compliance with participation requirements. Outcomes include both actual and potential negative outcomes, as well as failure of a facility to help residents achieve their highest practicable level of well-being. Based on the specific procedures detailed in this appendix, a standard survey assesses:

- o Compliance with residents' rights and quality of life requirements;

- o The accuracy of residents' comprehensive assessments and the adequacy of care plans based on these assessments;

o The quality of care and services furnished, as measured by indicators of medical, nursing, rehabilitative care and drug therapy, dietary and nutrition services, activities and social participation, sanitation and infection control; and

o The effectiveness of the physical environment to empower residents, accommodate resident needs, and maintain resident safety, including whether requested room variances meet health, safety, and quality of life needs for the affected residents.

2. Extended Survey.--The extended survey is conducted after substandard quality of care is determined during a standard survey. If, based on performing the resident-centered tasks of the standard survey you make a determination that the facility has provided substandard quality of care in 42 CFR 483.13, Resident Behavior and Facility Practices; 42 CFR 483.15, Quality of Life; and/or 42 CFR 483.25, Quality of Care, then you must conduct an extended survey within 14 days after completion of a standard survey. (See Appendix P, Part I, Section III, the extended and partial extended survey.)

3. Abbreviated Standard Survey.--This survey focuses on particular tasks that relate, for example, to complaints received or a change of ownership, management or director of nursing. The abbreviated standard survey does not cover all the aspects covered in the standard survey, but rather concentrates on a particular area of concern or concerns. For example, an abbreviated standard survey may be conducted to substantiate a complaint. The survey team can expand the abbreviated standard survey to cover additional areas, or to a standard survey if, during the abbreviated standard survey, they find evidence that warrants a more extensive review.

4. Partial Extended Survey.--A partial extended survey is always conducted after substandard quality of care is found during an abbreviated standard survey or during a revisit, when substandard quality of care was not previously identified. If, based on performing the abbreviated standard survey or revisit you make a determination that the facility has provided substandard quality of care in 42 CFR 483.13, Resident Behavior and Facility Practices; 42 CFR 483.15, Quality of Life; and/or 42 CFR 483.25, Quality of Care, then you must conduct a partial extended survey. (See Appendix P, Part I, Section III, the extended and partial extended survey.)

5. Post-Survey Revisit (Follow-up).--The post-survey revisit is an on-site visit intended to verify correction of deficiencies cited in a prior survey. See §2732 and Appendix P, Part I, Section VI. If substandard quality of care is determined during a revisit, complete a partial extended survey, if a partial extended or extended survey had not been conducted as the result of the prior standard or abbreviated standard survey.

B. Initial Certification Survey.--In a survey for initial certification of SNFs or NFs, perform the tasks of both the standard and extended surveys. During the initial survey, focus both on residents and the structural requirements that relate to qualification standards and resident rights notification, whether or not you identify problems during the information gathering tasks. Gather additional information to verify compliance with every tag number. For example, during an initial survey verify the qualifications of the social worker, dietitian, and activities professional. Also, review the rights notification statements on admissions contracts. Complete the Statement of Deficiencies and Plan of Correction (Form HCFA-2567) in Exhibit 7.

C. Specialty Surveyors.--All members of a survey team need not be onsite for the entire survey. Specialty surveyors participating in surveys (e.g., a pharmacist, physician, or registered

dietitian) may be onsite only during that portion of the survey dealing with their area of expertise. However, they must conduct that portion while the rest of the team is present. All members of the survey team should enter the facility at the same time, if possible. Before leaving the facility, at the completion of his/her portion of the survey, the specialty surveyor must meet with the team or team coordinator to discuss his/her findings and to provide supporting documentation. The specialty surveyor should also share any information he/she obtained that may be useful to other team members. If he or she is not present at the information analysis for deficiency determination, the specialty surveyor should be available by telephone at that time and during the exit conference.

D. Team Communication.--Throughout the survey process, the team (including specialty surveyors onsite at the time) should discuss among themselves, on a daily basis, observations made and information obtained in order to focus on the concerns of each team member, to facilitate information gathering and to facilitate decision making at the completion of the standard survey.

II. THE SURVEY TASKS

TASK 1 - OFFSITE SURVEY PREPARATION

A. General Objectives.--The objectives of offsite survey preparation are to analyze various sources of information available about the facility in order to:

- Identify and pre-select concerns for Phase 1 of the survey, based on the Facility Quality Indicator Profile (see description below at B.3.a.). (This pre-selection is subject to amendment based on the results of the tour.);

- Pre-select potential residents for Phase I of the survey based on the Resident Level Summary (see description below at B.3.a.) (This pre-selection is subject to amendment based on the results gathered during the tour, entrance conference, and facility Roster/Sample Matrix);

- Note concerns based on other sources of information listed below and note other potential residents who could be selected for the sample; and

- Determine if the areas of potential concerns or special features of the facility require the addition to the team of any specialty surveyors.

B. Information Sources for Offsite Survey Preparation.--The following sources of information (1-8) are used during the offsite team meeting to focus the survey.

1. Quality Indicator (QI) Reports from the Standard Analytic Reporting System of the HCFA National Resident Assessment Data Base.--(QIs are to be used as indicators of potential problems or concerns that warrant further investigation. They are not determinations of facility compliance with the long term care requirements.) There are three QI reports which can be downloaded from the State data base:

- Facility Characteristics (Exhibit 268).--Provides demographic information about the resident population (in percentages) for a selected facility compared to all the facilities in the State. This report is read left to right. It provides information such as gender and age of residents, payment source, diagnostic characteristics, assessments completed by type, and a summary of the number of assessments completed per month.

o Facility Quality Indicator Profile (Exhibit 269).--Provides facility status for each of the MDS-based QIs as compared to a peer group of the facilities in the State. The report is read left to right. Listed are the individual QIs (grouped by Domains). For each QI, (reading across a row) are:

- The numerator - the number of residents in the facility who have the QI condition;
- The denominator - the number of residents in the facility who could have the QI condition;
- The facility percentage of residents who have the QI condition;
- The State percentage of residents who have the QI condition;
- The percentile ranking of the facility on the QI - a descriptor of how the facility compares (ranks) with other facilities in the state. The higher the percentile rank, the greater potential there is for a care concern in the facility; and
- A flag is present in any row in which the facility "flags" on an indicator, which means that facility is at or above the 90th percentile; or a flag is present in one of the three sentinel event QI rows if any resident has the condition. (See D. below for more information.)

o Resident Level Summary (Exhibit 270).--Provides resident-specific QI information. This report is generated using the most current MDS records in the State data base at the time the report was generated, including all residents who have an MDS in the system. It is used to preselect residents for the Phase 1 sample who have conditions representing the concerns selected using the Facility Quality Indicator Profile. Reading from left to right, the report lists:

- Each resident in alphabetical order;
- MDS date and type of assessment:
  + A = admission;
  + Y = any full assessment (annual, significant change, or significant correction);
  + Q = quarterly;
  + O = other; and
  + M, when added to A, Y, Q, or O = also coded as a Medicare assessment.
- Columns which list each QI with subcolumns for high and low risk; and
- The total number of QIs flagged for the resident.

A checkmark (✓) appears in a QI column for a resident who has that QI condition. If a QI is risk adjusted, this checkmark (✓) is in either the high or low risk subcolumn for the QI, indicating

whether this resident was at high or low risk to develop the QI condition. This specification of high or low risk can help survey teams to select which residents to review. If the team has selected incontinence as a QI concern, it may be most productive to select residents for whom incontinence would not have been expected (those at low risk).

NOTE: Resident-specific information in the Resident Level Summary must be kept confidential according to the Privacy Act. The report is only for the use of the State agency, HCFA representatives, and the facility.

2 The Statement of Deficiencies (HCFA-2567) and Statement of Isolated Deficiencies Which Cause No Actual Harm With Only Potential For Minimal Harm (Form A).-- These statements of deficiencies from the previous survey should be reviewed, along with the sample resident identifiers list. Review the specific information under each deficiency and note any special areas of concern. For example, a deficiency was cited for comprehensive care planning last year. Share with the team the specific care planning problems that were listed as the reasons for this deficiency. For resident-centered requirements, determine if any residents identified in the deficiency might be good candidates for the sample. For example, a deficiency was cited for abuse partly based on surveyor observation of a staff member striking a resident who was combative. Identify this resident by name and add the name to the Offsite Preparation Worksheet. (During the Initial Tour, evaluate this resident for inclusion in the sample.)

3. OSCAR Report 3, History Facility Profile, and OSCAR Report 4, Full Facility Profile from HCFA's OSCAR Computer System.--(Refer to Exhibit 96 for sample copies of Reports 3 and 4.) Report 3 contains the compliance history of the facility over the past 4 surveys. Use it to determine if the facility has patterns of repeat deficiencies in particular tags or related tags. This report also lists the dates of any complaint investigations and Federal monitoring surveys during the 4 year time period.

Report 4 contains information provided by the facility during the previous survey on the Resident Census (HCFA-672). This report compares facility population characteristics with State, HCFA region, and national averages.

4. Results of Complaint Investigations.--Review information from both complaints investigated since the previous standard survey and complaints filed with the survey agency, but not yet investigated. Note resident and staff names related to the complaints and note patterns of problems relating to specific wings or shifts.

5. Information about Waivers or Variances.--If the facility has, or has requested any staffing waiver or room variances, note these for onsite review. The team will determine onsite if these should be granted, continued, or revoked due to a negative effect on resident care or quality of life.

6. Information from the State Ombudsman Office.--Note any potential areas of concern reported by the ombudsman office and note resident names reported as potential sample residents, residents for closed record review, or family members for family interviews and the reasons for their recommendation by the ombudsman.

7. Preadmission Screening and Resident Review Reports (PASRR).--Some States may have formal mechanisms to share with the survey agency the results of PASRR screens for residents with mental illness or mental retardation. If this information is available, evaluate if there are any potential concerns and note names of residents for possible inclusion in the sample.

8. Other Pertinent Information.--At times, the survey agency may be aware of special potential areas of concern that were reported in the news media or through other sources. Evaluate this information to determine if there are potential areas of concern that should be investigated onsite.

C. Team Coordinator Responsibilities.--The team coordinator (and/or designee) is responsible for completing the following tasks:

1. Contact the ombudsman office in accordance with the policy developed between the State survey agency and State ombudsman agency. The purposes of this contact are to notify the ombudsman of the proposed day of entrance into the facility and to obtain any information the ombudsman wishes to share with the survey team. Ask if the ombudsman will be available if residents participating in the group or individual interviews wish her/him to be present.

2. Obtain all information sources listed in B. above for presentation at the offsite team meeting. (See Section B. for descriptive information about these reports.) They are as follows:

- o Quality Indicator (QI) Reports:
  - Facility Characteristics Report;
  - Facility Quality Indicator Profile; and
  - Resident Level Summary;

NOTE: It is important that the QI reports be generated as close to the date of survey as possible, preferably no more than a few days prior to the survey.

- o Form HCFA-2567 and Statement of Isolated Deficiencies Which Cause No Actual Harm With Only Potential For Minimal Harm;
- o Standard OSCAR Report 3 and 4;
- o Results of complaint investigations;
- o Information about waivers or variances;
- o Information from the State Ombudsman office;
- o Preadmission Screening and Resident Review Reports; and
- o Other pertinent information.

3. Complete the following additional duties:

- o Copy and distribute to the team the facility's floor plan if the team is unfamiliar with the facility's layout;
- o Make extra copies of the OSCAR Reports 3 and 4, and the three QI reports to be given to the facility's administrator;
- o Obtain an extra copy of the group interview worksheet (see HCFA-806B, Exhibit 94) to give to the council president.

o If the State does not use an alternate mechanism to obtain the ownership disclosure information, in accord with 42 CFR 420.206(b) for Medicare facilities, obtain ownership disclosure forms; HCFA-1513 (Exhibit 6), HCFA-855, (Exhibit 256) and/or HCFA- 855C (Exhibit 257). If the facility has already completed a HCFA-855 and no changes have occurred since that filing, the facility may present a copy of the previously filed HCFA-855. If changes have occurred since filing the HCFA-855, the facility will need to complete a new HCFA-855 or HCFA-855C as directed by §2005 of the State Operations Manual. If the faciltiy has not previously filed a HCFA-855 and has had a change of ownership, a HCFA-855 must be completed. In other cases (including Medicaid facilities), the facility must complete a Form HCFA-1513.

D. Offsite Survey Preparation Team Meeting.--Present copies of the information obtained to the survey team members for review at a team meeting offsite. The team must prepare for the survey offsite, so they are ready to begin the Entrance Conference and Initial Tour immediately after they enter the facility. The team should:

1. Review the Facility Characteristics report to note the facility's demographics. This report can be used to identify whether the facility's population is unusual (high prevalence of young or male residents, high prevalence of residents with psychiatric diagnosis, high percentage of significant change assessments, etc.).

2. Use a copy of the Roster/Sample Matrix (Form HCFA-802, Exhibit 90) to highlight concerns the team identifies for Phase 1 of the survey, and to list residents preselected and the QI conditions for which each was selected. Mark the offsite block on this form to distinguish it from the Phase 1 version that will be completed in Task 4. Use the Facility Quality Indicator Profile to select concerns based on the following:

o Any sentinel health event QI that is flagged. A "sentinel health event" is a QI that represents a significant occurrence that should be selected as a concern, even if it applies to only one or a few residents. The sentinel event QIs are Prevalence of Fecal Impaction, Prevalence of Dehydration, and Prevalence of Pressure Ulcers (low risk). This means that if even one resident has any of these conditions, this QI will flag and the care area must be selected as a concern and the resident with the problem must be selected for the sample (if there are multiple residents who flag on a sentinel event QI, it is not necessary to select all of them);

o Any other QI that is flagged (at the 90th percentile); and

o Any unflagged QI in which the facility is at the 75th percentile or greater.

The survey team may also wish to select as concerns any other QIs that are of interest to them because they are related to QIs that have been selected, or because their percentile number is extremely low in comparison to the remaining QIs. They may also select other areas of concern derived from sources of information other than the QI reports.

3. Preselect potential residents for the Phase 1 sample to represent the concerns that have been selected, including selecting residents who have sentinel event QI conditions (if multiple residents have a sentinel event QI condition, it is not necessary to select all of them). Use Table 1 in this section and the number of the total resident census to determine the sample size for the Phase 1 sample. Preselect a few more residents (three to five) than the actual number that will be required for the Phase 1 sample to accommodate the fact that some residents who have been preselected may no longer be at the facility (these residents could fill Closed Record slots on the sample).

o In any facility in which the team has noted concerns with weight loss, dehydration, and/or pressure sores, select approximately ½ of the preselected sample as residents who have one or more of these conditions. For the condition of hydration, you must select a resident who

has flagged for the sentinel event QI #15(dehydration) and you may select residents with any of the following QI conditons: #11 - Fecal Impaction; #12 - Urinary tract infections; #13 - weight loss; #14 - Tube feeding; and #17 - Decline in Activities of Daily Living (ADL's). The best residents to select will be those who also have multiple care areas that have been selected as concerns. In any facility in which these concerns were not identified, the team should still select some residents who have these QI conditions (if any) on the Resident Level Summary, but this need not be 50% of the Phase 1 sample size.

o For the remaining half of the Phase 1 preliminary sample, select residents to represent the remaining areas of concern.

NOTE: If there are no other QIs that have been selected as concerns, the team may select residents based on other sources of information (such as complaints, or a report from the ombudsman) or may wait to select the remaining Phase 1 residents based on Initial Tour findings.

If the average length of stay for the facility's population is less than 14 days, there may be little quality indicator or resident specific QI information available. Preselection of QI based concerns and/or the full sample may not be possible. Selection of some or all concerns and residents may need to be totally conducted onsite.

o The survey team should be alert to inconsistencies on the Facility Quality Indicator Profile that may indicate facility error in completing and/or transmitting its Minimum Data Set (MDS) records, or a problem with State's software or HCFAs data base. The following are some possible indicators of data quality problems:

- The denominator for QIs that use "all residents" substantially exceeds or is substantially smaller than the facility bed size;

- The number of residents with a QI condition (i.e., the numerator) exceeds the resident population; or

- The numerator for a particular QI is zero although other information sources indicate otherwise. For example, the QI report shows zero residents in restraints, but the ombudsman notified the team that she/he verified complaints about restraints. The most common reason for this type of inconsistency is incorrect MDS coding by the facility.

If these or other potential accuracy concerns are noted, the team should add resident assessment accuracy as a concern for the survey.

NOTE: This review need not be done for "short-stay" facilities, which will often have unusual values in the numerator and denominator, due to rapid turnover of residents.

The Facility Quality Indicator Profile is generated using the most current MDS records in the State data base at the time the report was generated. However, it excludes residents who have only an initial MDS record in the system. This was done so that the report reflects the care residents have received while residing in the facility, as opposed to the conditions of residents at the time of admission to the facility. The Resident Level Summary is calculated using the most recently transmitted MDS record (e.g., annual, significant change, quarterly, or initial MDS record). You could see differences between the Facility Quality Indicator Profile and the Resident Level Summary since the facility profile does not use the admission MDS data. For example, the Resident Level Summary may indicate a resident had a catheter, but the Facility Quality Indicator Profile might show a "0". This is not an accuracy problem, it only reflects the use of different data to generate each report.

4. Review the OSCAR reports after the review of the QI reports to add corroborative information to the QI information (e.g., a pattern of repeat deficiencies in a requirement related to a flagged QI) and/or to point out areas of large discrepancies between the QI Facility Quality Indicator Profile and the OSCAR Reports (e.g., the OSCAR 4 report lists the facility as having triple the average number of residents in restraints, but the QI report shows the facility has less restraints than most facilities). The team coordinator may wish to discuss such discrepancies with the administrator on entrance to determine the reason for them.

Relate information between Reports 3 and 4 such as a pattern of repeat deficiencies in range of motion and a lower than average percentage of residents receiving rehabilitative services. Also, note any special resident characteristics not contained in the QI reports.

NOTE: Both the OSCAR reports and the QI reports can alert surveyors to the acuity and characteristics of the facility's residents at the time the information for these reports was determined. This information may not represent the current condition of residents in the facility at the time of the survey. Keep in mind that the OSCAR information is approximately one year old, and the QI information may be from two to six months old. Resident characteristics that were reported by the facility during the last survey may have changed significantly and may be the source of some discrepancies between OSCAR and QI information.

5. Review all other sources of information and record additional information on the Offsite Preparation Worksheet (Form HCFA-801, Exhibit 89), for example, residents' names for possible inclusion in the Phase 2 sample based on non-QI sources of information (B. 2 through 8 above), special features of the facility, or special resident populations. Identify any outstanding complaints needing investigation. At this meeting, establish preliminary surveyor assignments and projections of which days team members will enter early and/or stay late to make observations of resident care and quality of life.

TASK 2 - ENTRANCE CONFERENCE/ONSITE PREPARATORY ACTIVITIES

A. Entrance Conference.--

1. The team coordinator informs the facility's administrator about the survey and introduces team members.

2. After the introduction to the administrator, the other team members should proceed to the Initial Tour (Task 3), while the team coordinator conducts the entrance conference.

3. The team coordinator should:

o Request a copy of the actual working schedules for licensed and registered nursing staff for this time period by the end of the tour or earlier if possible.

o Inform facility staff that the survey team will be communicating with them throughout the survey and will ask for facility assistance when needed. (See §2713A for further information about facility staff accompanying surveyors.) Advise them that they have the opportunity to provide the team with any information that would clarify an issue brought to their attention.

o Explain the survey process and answer any questions from facility staff.

o Give the administrator copies of the three QI reports and the OSCAR 3 and

4 reports that are being used for the survey. Briefly explain these reports and how they were used by the survey team in Task 1. If there are discrepancies between the OSCAR information and the QI Facility Characteristics report, ask the administrator or person designated by the administrator to explain the discrepancies.

o Ask the administrator to describe any special features of the facility's care and treatment programs, organization, and resident case-mix. For example, does the facility have a special care unit for residents with dementia? Are residents with heavy care needs placed in particular units? If so, which ones?

o Inform the administrator that there will be interviews with individual residents, groups of residents, family members, friends, and legal representatives, and that these interviews are conducted privately, unless the interviewees request the presence of a staff member. Ask the administrator to ensure that there are times during the survey when residents can contact the survey team without facility staff present and without having to ask facility staff to leave or to allow access to the team.

o Ask the administrator to provide the following information within one hour of the conclusion of the Entrance Conference (or later at the survey team's option):

1. List of key facility personnel and their locations (such as: the administrator; directors of finance, nursing services, social services, and activities; dietitian or food supervisor; rehabilitation services staff; charge nurses; pharmacy consultant; plant engineer; housekeeping supervisor; persons responsible for infection control and quality assurance; health information management professional; and the medical director);

2. A copy of the written information that is provided to residents regarding their rights;

3. Meal times, dining locations, copies of all menus, including therapeutic menus, that will be served for the duration of the survey;

4. Medication pass times (by unit, if variable);

5. List of admissions during the past month, and a list of residents transferred or discharged during the past 3 months with destinations;

6. A copy of the facility's layout, indicating the location of nurses' stations, individual resident rooms, and common areas, if not obtained in Task 1;

7. A copy of the facility admission contract(s) for all residents. (Medicare, Medicaid, other payment sources);

8. Facility policies and procedures to prohibit and investigate allegations of abuse and the name of a person the administrator designates to answer questions about what the facility does to prevent abuse (see Task 5G Abuse Prohibition Review for further information);

9. Evidence that the facility, on a routine basis, monitors accidents and other incidents, records these in the clinical or other record; and has in place a system to prevent and/or minimize further accidents and incidents;

NOTE: This evidence, at the discretion of the facility, could include or be a record of accident and incident reports.

10. The current resident activity schedule/calendar;

NOTE: The facility is not required by Federal regulations to maintain this record.

11. The names of any residents age 55 and under; and

12. The names of any residents who communicate with non-oral communication devices, sign language, or who speak a language other than the dominant language of the facility.

o Ask the facility to complete the Roster/Sample Matrix (HCFA-802), including all residents on bedhold to the best of their ability by the end of the Initial Tour, or to provide this information in some other format (e.g., computer-generated list).

NOTE: This is an important source of resident information, which is crucial for the team to have for their sample selection meetings. Stress to the facility that this form should be completed first and given to the team coordinator by the end of the Initial Tour. After the Roster/Sample Matrix is delivered to the team, the facility may make modifications for accuracy or add additional information within 24 hours.

o Ask the facility to provide, within 24 hours of the Entrance Conference:

1. A completed Long Term Care Facility Application for Medicare and Medicaid (HCFA-671), (See Exhibit 85); A Resident Census and Conditions of Residents (HCFA - 672), (See Exhibit 86); and the completed ownership document (HCFA-1513, or HCFA-855), if not obtained through other State mechanisms;

2. A list of Medicare residents who requested demand bills in the last 6 months (SNFs or dually-participating SNF/NFs only).

o Also, ask the administrator the following questions:

1. Which, if any, rooms have less square footage than required? Do you have a variance in effect and are you prepared to continue to request a variance for any such rooms? (F458)

2. Which, if any, rooms are occupied by more than four residents? Do you have a variance in effect and are you prepared to continue to request a variance for any such rooms? (F457)

3. Is there at least one window to the outside in each room? (F461)

4. Which, if any, bedrooms are not at or above ground level? (F461)

5. Do all bedrooms have access to an exit corridor? (F459)

6. What are the procedures to ensure water is available to essential areas when there is a loss of normal supply? (F466)

NOTE: If the survey is commencing at times beyond the business hours of 8:00 a.m. to 6:00 p.m., or on a Saturday or Sunday, once onsite, announce the survey, ascertain who is in charge, ask the person to notify the administrator that a survey has begun. Modify the entrance conference in accordance with staff available and complete the task and the onsite preparatory activity as appropriate within the context of the survey.

B. Onsite Preparatory Activities.--

1. In areas easily observable by residents and visitors, post (or ask the facility to post) signs announcing that you are performing a survey and are available to meet with residents in private.

2. The team coordinator or designee should contact the resident council president after the Entrance Conference to introduce him/herself and to announce the survey. Provide the president with a copy of the group interview questions. Request the assistance of the president for arranging the group interview and to solicit any comments or concerns. Ask the council president for permission to review council minutes for the past 3 months (see Task 5D, Section 3B for further information). If there is not an active resident council, or if the council does not have officers, ask for a list of residents who attend group meetings (if any), and select a resident representative to assist in arranging the group interview. If the ombudsman has indicated interest in attending the group interview, ask the president if it is all right with the group that the ombudsman attend the meeting. If the reply is affirmative, notify the ombudsman of the time/place of the meeting.

3. The team coordinator, the surveyor assigned to conduct the group interview, or a designee should arrange for date, time and private meeting space for the interview. Advise the facility staff that non-interviewable residents are not part of this meeting. (See Task 5D for further guidance.)

TASK 3 - INITIAL TOUR

A. General Objectives.--The Initial Tour is designed to:

- Provide you with an initial review of the facility, the residents and the staff;
- Obtain an initial evaluation of the environment of the facility, including the facility kitchen;
- Confirm or invalidate the preselected concerns (if any) and add concerns discovered onsite.

B. General Procedures.--The initial tour is used to gather information about concerns which have been preselected; new concerns discovered onsite; and whether residents preselected for the Phase 1 sample offsite are still present in the facility. In addition, during the tour, attempt to meet and talk with as many residents as possible in order to identify other candidates for the sample, to get an initial overview of facility care and services, to observe staff/resident interactions; and to evaluate the impact of the facility environment on the residents. The tour also includes a first brief look at the facility kitchen.

Document tour information, on either the Roster/Sample Matrix (HCFA-802), or the Surveyor Notes Worksheet (HCFA-807). Document any concerns regarding the general environment on the General Observations of the Facility Worksheet, (HCFA-803) or Surveyor Notes Worksheets, (HCFA-807). (See Task 5A for further information.) Surveyors may also document notes on the facility's Roster/Sample Matrix or other list of residents provided by the facility. Document any concerns noted in the brief tour of the facility kitchen on the Kitchen/Food Service Observation worksheet (HCFA-804, Exhibit 92). (See Task 5B for information regarding observations to make during this brief tour.)

C. Protocol.--Surveyors should tour individually as assigned by the team coordinator. It is desirable for team members to have a facility staff person who is familiar with the residents

accompanying them during the tour to answer questions and provide introductions to residents or family. However, do not delay the beginning of the Initial Tour if facility staff are not available. Begin the tour as soon as possible after entering the facility.

NOTE: When standard surveys begin at times beyond the business hours of 8:00 a.m. to 6:00 p.m., or begin on a Saturday or Sunday, the initial tour will need to be modified in recognition of the residents' activity (e.g., sleep, religious services) and types and numbers of staff available upon entry. The tour may focus on specific care and quality of life issues such as: restraint use, meal service, use of foam or paper meal service products rather than regular dinnerware, adherence to the planned menu; sufficiency of staff; whether enteral/parenteral fluids are being administered as ordered; whether incontinent residents are being checked, toileted, changed; etc. as appropriate. The tour should not be delayed for lack of staff to accompany the surveyor and/or survey team.

Phase 1-- Pre-selected Concerns and Potential Residents:

During the tour, be sure to determine for each resident pre-selected offsite for the Phase 1sample whether the resident is still there. Determine which (if any) of the preselected Phase 1 sample residents are interviewable residents who can be selected to participate in a Quality of Life Assessment Resident Interview or Group Interview. (See Task 5D.) This can be accomplished by talking with residents and asking questions. Examples of questions that can be used are: What is your name? What are you planning to do today?

NOTE: Do not rely solely on the information that the facility provides concerning which residents are interviewable. The survey team should determine the residents who are able to participate in a Quality of Life Assessment interview.

If possible, determine if there are family members of non-interviewable residents in the preselected Phase 1 sample who can be selected for a Quality of Life Assessment family interview. Also note other non-interviewable residents among the facility population whose family members could be selected for interviews;

Observations of All Residents During the Tour:

Ask staff to identify those residents who have no family or significant others. The team may include one or more of these residents in the Phase 2 sample for investigation of quality of life issues.

Have staff identify newly admitted residents (who have been admitted within the past 14 days) for possible inclusion in the sample for investigation of decline or deterioration that may have occurred before all MDS, other resident assessment information, and care planning is completed.

Have staff identify any residents for whom transfer or discharge is planned within the next 30 days.

Note residents who are interviewable or who have special factors, as listed in Task 4. When on the Initial Tour, observe and document possible quality of care and quality of life concerns in addition to those preselected offsite. If observed concerns involve specific residents, note the resident's name and room number on the worksheet, and the date/time when describing the observed concern. Include in your documentation the details of your observation including any effects on the residents involved.

Conduct a brief initial observation of the kitchen. See Task 5B for further information.

While on tour, identify the licensed and registered nursing staff who are currently on duty, and later at the end of the tour, compare the observed staff with the duty roster the facility is to provide. If there are discrepancies between the duty roster and the staff observed onsite, ask the person in charge to explain the discrepancies. (This information will be used in Task 6 to determine if the facility is compliant with the requirements for licensed and registered nursing staff at 42 CFR 483.30(a)(2), F353 and 42 CFR 483.30(b)(1), F354.)

During the tour focus on the following:

o Quality of Life:.--

1. Resident grooming and dress, including appropriate footwear;

2. Staff-resident interaction related to residents' dignity; privacy and care needs, including staff availability and responsiveness to residents' requests for assistance;

3. The way staff talk to residents, the nature and manner of interactions, and whether residents are spoken to when care is given; and

4. Scheduled activities taking place and appropriateness to the residents.

o Emotional and behavioral conduct of the residents and the reactions and interventions by the staff:.--

1. Resident behaviors such as crying out, disrobing, agitation, rocking, pacing; and

2. The manner in which these behaviors are being addressed by staff, including nature and manner of staff interactions, response time, staff availability, and staff means of dealing with residents who are experiencing catastrophic reactions. (See Abuse Prohibition Investigative Protocol in Task 5G for a definition of catastrophic reaction.)

o Care issues, how care is provided, and prevalence of special care needs.--

1. Skin conditions (such as excessive dryness, wetness);

2. Skin tears, bruising, or evidence of fractures that warrant investigation;

3. Dehydration risk factors including availability of water for most residents, and other indicators or factors such as, the amount and color of urine in tubing and collection bags, dependence on staff, the presence of strong urinary odors, and resident complaints of dry mouth and lips;

4. Clinical signs such as edema, emaciation and contractures;

5. Functional risk factors such as poor positioning and use of physical restraints;

6. Side effects of antipsychotic drug use such as tardive dyskinesia (e.g., lip, tongue or other involuntary abnormal movements);

7. Presence or prevalence (numbers) of infections including antibiotic resistant strains of bacteria (e.g., Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), Clostridium Difficile (C-Diff) or other infections: urinary tract infections, draining wounds, eye infections, skin rashes (especially if spreading, undiagnosed, and/or not responding to treatment), respiratory infections, gastroenteritis including diarrhea, etc.

8. Pressure sores, old scars from pressure sores or evidence of surgical repair of pressure sores;

9. Amputation;

10. Significant weight loss;

11. Feeding tubes and/or improper positioning while feeding is infusing; and

12. Ventilators, oxygen, or intravenous therapies.

o Impact of the facility environment and safety issues.--

1. Infection control practices (such as handwashing, glove use, and isolation procedures);

2. Functional and clean equipment, including kitchen equipment;

3. Presentation and maintenance of a homelike and clean environment; and

4. Availability, use and maintenance of assistive devices.

NOTE: If the initial tour is being conducted during a mealtime, include an initial brief observation of the dining areas. Note if there are any concerns with meal service, quality of life, positioning, sufficient space, etc.

TASK 4 - SAMPLE SELECTION

A. General Objective.--The objective of this task is to select a case-mix stratified sample (see Special Factors to Consider in Sample Selection below for further information) of facility residents based on QIs and other offsite and onsite sources of information in order to assess compliance with the resident-centered long term care requirements.

B. General Procedures.--

o The Phase 1 sample is preselected during Task 1, Offsite Survey Preparation, based on QIs and other areas of concern. The preselected sample is reviewed during the sample selection meeting and residents are retained for the sample unless they are discharged, or the survey team has another reason to substitute (e.g., to select interviewable residents). Each team member is assigned to review a certain number of residents, completing all facets of review that have been selected including any quality of life assessment protocols selected for these residents.

o The Phase 2 sample is selected onsite, part way through the survey when surveyors have collected enough information to determine the focus of the remainder of the survey. The Phase 2 sample residents are selected to represent new concerns and/or to continue further investigation of Phase 1 concerns when Phase 1 reviews proved inconclusive or when necessary to determine scope of a problem. It is statutorily required that the sample in each facility be case-mix stratified in order to capture both interviewable and non-interviewable residents, and residents from both heavy and light care categories.

NOTE: If the team is conducting sample selection during a meal time, delay or interrupt this task to conduct brief observations of the dining areas. Note if there are any concerns with meal service, quality of life, positioning, sufficient space, etc.

C. Definitions.--

o Interviewable Resident.--This is a resident who has sufficient memory and comprehension to be able to answer coherently the majority of questions contained in the Resident Interview. These residents can make day-to-day decisions in a fairly consistent and organized manner.

o Comprehensive Review.--For Task 5C, Resident Review, this includes observations, interviews, and record reviews for all care areas for the sampled residents as applicable.

o Focused Review.--For Task 5C, Resident Review, this includes the following:

- For Phase 1: Observations, interviews and record reviews concerning all highlighted areas of concern and all unhighlighted areas pertinent to the resident;

- For Phase 2: Observations, interviews and record review for all highlighted areas of concern pertinent to the resident.

o Closed Record Review.--For Task 5C, Resident Review, this includes a record review of residents' care issues and transfer and discharge.

o Roster/Sample Matrix.--This worksheet, (Exhibit 265, Form HCFA-802), is used by the survey team during Offsite Survey Preparation, and at the Phase 1 and Phase 2 Sample Selection meetings to note areas of concern for the survey, and to select residents for the sample. There are separate sets of instructions for the use of this form by the survey team and the facility. (See these instructions at Exhibits 266 and 267.

D. Protocol.--

1. Phase 1 - Sample Selection.--The Phase 1 sample is preselected during Task 1, Offsite Survey Preparation, based on the facility's QIs of concern. (See Task 1 for further information.) Final phase 1 sample selection occurs after the tour is completed and the facility has provided the completed Roster/Sample Matrix (Form HCFA-802, Exhibit 265), or to provide this information in some other format (e.g., computer-generated list). However, do not delay Phase 1 sample selection if the facility's Roster/Sample Matrix has not arrived. The team will complete the sample selection for Phase 1 by performing the following tasks:

NOTE: For facilities with a population of "short-stay" residents, the team may not have been able to preselect concerns or potential sampled residents. In that instance Phase 1 sample selection will occur during this task.

o First determine if any preselected concerns should be dropped due to the QI data not representing the conditions of current residents. For example, there was a preselected QI concern with residents with tube feedings, but the tour has verified there are no residents in the facility who are receiving tube feedings. Note new concerns and determine if some preselected residents can be evaluated for the new concerns, as well as those originally selected.

o Review the Roster/Sample Matrix provided by the facility and compare it to the findings from the tour to determine if there is a reason to substitute another resident for any of the residents from the Offsite sample. A preselected resident who is no longer in the facility can be considered for the closed record review. The team may substitute other residents for those preselected, if necessary. They can select either from the QI reports, the tour, or the facility=s Roster/Sample Matrix.

If any resident is substituted for a preselected resident, record a short explanation on the Offsite Roster/Sample Matrix next to that person's name (e.g., "discharged").

o Check "Phase 1" on the copy of the Roster/Sample Matrix that will be used to denote the resident sample for Phase 1 of the survey.

- Highlight the column for each identified concern for Phase 1.

- Use Table 1 in this section and the number of the total resident census to determine the number of comprehensive and focused reviews, number of closed records, number of resident and family interviews, and the minimum number of residents who have conditions of weight loss, hydration risk and/or pressure sores (the WHP group) . The number in the WHP column represents the minimum total of residents who must be selected for the Phase 1 sample to represent any or all of these conditions. For example, out of 12 residents selected for the Phase 1 sample, in a facility with 96 residents, a minimum of 6 will be those who have any of the conditions mentioned above, if any of these 3 QIs were selected as concerns.

- Use the unnumbered blocks to the right of Resident Name to fill in the total number of residents in each subsample for the entire survey as listed in Table 1. For example, in a facility with a census of 100, the total number of individual interviews is 5. Enter that number in the small block below that title.

- All residents selected for comprehensive reviews are selected by the team during the Phase 1 sample selection. Residents selected for focused reviews, closed record reviews, individual and family interviews may be selected during Phase 1 or Phase 2 sample selection.

- Each resident the team selects is entered on the worksheet. Note the following about each resident:

+ Resident number and room number;

+ Surveyor assigned to complete the resident review and any quality of life assessment protocols (Resident Interview or Family Interview) that are selected for the resident;

+ Check any columns that pertain to this resident, whether or not they are highlighted as concerns for Phase 1 (each resident will be reviewed for each checked area, not just those that are highlighted); and

+ If there is anything about this resident that the team decides to investigate that is not one of the numbered columns on the worksheet, use a blank column at the far right to write the item that will be assessed, and check that column for that resident. For example, if the team wants to assess ventilator use for a particular resident, write "ventilator" in one of the blank columns and make a check mark in that column for that resident.

2. Phase 2 Sample Selection.--Part way through the survey, after the team has obtained enough information to decide what concerns need further investigation, the team meets to determine the areas of concern (if any) for Phase 2 of the survey and to select the remaining sample. It is not necessary to complete all the reviews of all residents in Phase 1 before this meeting. Determine which Phase 1 concerns are ruled out as these do not need to be carried over into Phase 2 sample selection.

o Select concerns for Phase 2 based on the following:

- Initial concerns noted during Offsite Survey Preparation or the Initial Tour that have not been reviewed as yet;

- Currently unreviewed concerns that are related to those under investigation (e.g., adding residents who have had falls based on results of the Phase 1 discovery of a problem with use of psychoactive drugs); and

- Current concerns for which the information gathered is inconclusive.

o Select residents for the Phase 2 sample based on the following:

- It is a statutory requirement to select a "case mix stratified" sample (but not for each phase of the sample selection, just for the total sample). This stratification is defined by HCFA as including residents who are interviewable and non-interviewable, and as including residents who require heavy and light care. It is important that at least one resident in the sample represent each of these categories. The requirements of the sample selection procedures make it necessary for survey teams to select interviewable and non-interviewable residents in order to complete the Task 5D, Quality of Life Assessment Interviews, so those categories of case-mix stratification will be automatically filled by complying with the sample selection procedures. At the beginning of the Phase 2 sample selection meeting, the team should review the Phase 1 sample to determine if at least one heavy care and one light care resident has been selected to fulfill this portion of the case mix stratification requirement. If not, it is a priority to ensure that if either heavy or light care residents are missing from the Phase 1 sample, that at least one is selected from the missing category in Phase 2.

- Select residents who represent one or more of the areas of concern the team has selected for Phase 2 of the survey.

- If no residents have been selected for the Phase 1 sample for hydration, and if any residents are seen during Phase 1 of the survey who appear to have risk factors for dehydration, (e.g., such as residents who are dependent on staff for activities of daily living, are immobile, receive tube feedings, or have dementias in which the resident no longer recognizes thirst), select at least one of these residents at risk and review the care area of dehydration.

o During Phase 2 sample selection, a clean copy of the Sample/Matrix worksheet is used as follows:

- Check "Phase 2" on the copy of the Roster/Sample Matrix that will be used to denote the resident sample for Phase 2 of the survey;

- Highlight the column for each identified concern for Phase 2;

- Each resident the team selects is entered on the worksheet. Note the following about each resident:

+ Resident number and room number;

+ Surveyor assigned to complete the resident review and any quality of life assessment protocols (Resident Interview, or Family Interview) that are selected for the resident;

+ Checkmarks are made only in the highlighted columns and these residents will be reviewed for these concerns, and any other concerns that are discovered during this review;

+ Be sure that residents are selected to complete the required number of resident interviews, family interviews, and closed record reviews.

o If there are no outstanding areas of concern and the team has already selected interviewable, non-interviewable, heavy care and light care residents, then select remaining residents to represent any of the following (in no particular order):

- An area of concern on the worksheet that has not been highlighted, but which the team believes should be assessed;

- Living units that are unrepresented; and

- Special factors below that have not been reviewed.

NOTE: When selecting the sample in a facility in which there are no outstanding areas of concern, each resident will be reviewed for at least one area on the Roster/Sample Matrix that has not yet been reviewed.

3. Special Factors to Consider in Sample Selection.--Residents must be selected for both the Phase 1 and Phase 2 samples as representatives of concerns to be investigated and to fulfill the case mix stratified sample requirement. If during sample selection, you identify many more residents than can be selected to represent the concerns of interest, you may consider the factors below in your determination of which residents to select:

o New admissions, especially if admitted during the previous 14 days (even though the Resident Assessment Instrument (RAI) is not required to be completed for these residents, the facility must plan care from the first day of each resident's admission);

o Residents most at risk of neglect and abuse, i.e., residents who have dementia; no or infrequent visitors, psychosocial, interactive, and/or behavioral dysfunction; or residents who are bedfast and totally dependent on care;

o Residents in rooms in which variances have been granted for room size or number of beds in room;

o Residents receiving hospice services;

o Residents with end-stage renal disease;

o Residents under the age of 55;

o Residents with mental illness or mental retardation; and

o Residents who communicate with non-oral communication devices, sign language, or who speak a language other than the dominate language of the facility.

4. Other Phase 2 Tasks.--

o If there are any concerns about residents' funds, check that the amount of the surety bond is at least equal to the amount of residents' funds, the facility is managing as of the most recent quarter.

o If concerns have been identified in the area of infection control, review policies and procedures including a focus on what preventative infection control practices the facility has in place. For example, does the facility administer the influenza vaccine yearly to its residents, and

administer pneumococcal vaccine to new residents as appropriate (does facility evaluate whether new residents have received the pneumococcal vaccine within the last 5 years)?

o Complete Task 5F Quality Assessment Assurance Review.

o If the group interview has not occurred yet, discuss what special concerns to ask of the group.

o If the facility has or has requested a nurse staffing waiver, review the requirements at 42 CFR 483.30.

o Review the Resident Census and Condition of Residents (HCFA-672) that the facility has completed. Note any new areas of concern and determine if there appear to be large discrepancies between what is recorded by the facility and what the team has observed. (For example, the team has noted 13 residents with pressure sores and the facility has listed 3.) If there are large discrepancies, ask the facility to verify their totals. Answer questions F146-F148 on the Resident Census.

o If the team has identified quality of care problems during Phase 1 of the survey, use the investigative protocol at Task 5C: Nursing Services, Sufficient Staffing to gather information and (at Task 6) to determine compliance with the following requirement: 483.30(a), F353 Nursing services, sufficient staff. If problems with staffing have been discovered early in Phase 1, this protocol can begin in Phase 1.

5. Substituting Residents.--If the team has found it necessary during the survey to remove a resident from the sample (e.g., a resident refused to complete the interview), replace this resident with another who best fulfills the reasons the first person was selected. For example, the resident who was removed was selected because he/she was in restraints and had a pressure sore. Attempt to select another resident who meets both of these criteria. In Phase 1, the substituted resident should be selected from the preselected list of residents which was determined offsite, if possible, or from other information gained during the survey. Make the substitution as early in the survey as feasible. Note on the Roster/Sample Matrix that the new resident was substituted for resident #___ , and briefly give the reason the first resident was dropped.

6. Supplementary Sample.--If sampled residents are found not to provide enough information to make deficiency determinations concerning specific requirements under review, or to determine if there is "substandard quality of care" (see Task 6 for further information), supplement the sample with residents who represent the areas of concern under investigation. Focus review for these residents only on the concern under investigation and any other concerns that are discovered during this review. Add the names of these residents to the Phase 2 Sample Matrix worksheet, checking the relevant categories. Use the Resident Review Worksheet to complete these investigations.

TABLE 1
RESIDENT SAMPLE SELECTION

Resident Census	Phase 1/ Phase 2	Comprehensive Reviews *	Focused Reviews *	Closed Rec. Reviews *	Res./Family Interviews	W, H, P Group **
1 - 4	All / 0	2	2	0	1/1	All
5 - 10	3 / 2	2	2	1	1 / 1	2
11 - 20	5 / 3	2	5	1	2 / 2	3
21 - 40	6 / 4	2	7	1	3 / 2	3
41 - 44	7 / 4	2	8	1	3 / 2	4
45 - 48	7 / 5	2	9	1	3 / 2	4
49 - 52	8 / 5	3	9	1	4 / 2	4
53 - 56	8 / 6	3	9	2	4 / 2	4
57 - 75	9 / 6	4	9	2	4 / 2	5
76 / 80	10 / 6	4	9	3	4 / 2	5
81 - 85	10 / 7	4	10	3	4 / 2	5
86 - 90	11 / 7	4	11	3	4 / 2	6
91 - 95	11 / 8	4	12	3	4 / 2	6
96 - 100	12 / 8	5	12	3	5 / 2	6
101 - 105	13 / 8	5	13	3	5 / 2	7
106 - 110	13 / 9	5	14	3	5 / 2	7
111 - 115	14 / 9	5	15	3	5 / 2	7
116 - 160	14 / 10	5	16	3	5 / 2	7
161 - 166	15 / 10	5	17	3	5 / 2	8
167 - 173	16 / 10	5	18	3	5 / 2	8
174 - 180	16 / 11	5	19	3	5 / 2	8
181 - 186	17 / 11	5	20	3	5 / 2	9
187 - 193	17 / 12	5	21	3	5 / 2	9
194 - 299	18 / 12	5	22	3	5 / 2	9
300 - 400	18 / 12	5	22	3	6 / 3	9
401 -	18 / 12	5	22	3	7 / 3	9

* Comprehensive reviews plus focused reviews plus closed record reviews added together equals the total sample size (Phase 1 plus Phase 2).

** For any survey in which there are identified concerns in the areas of (W) unintended weight loss, (H) hydration, and/or (P) pressure sores, this is the minimum total of residents who must be selected for the Phase 1 sample to represent any or all of these conditions.

TASK 5 - INFORMATION GATHERING

Task 5 provides an organized, systematic, and consistent method of gathering information necessary to make decisions concerning whether the facility has met the requirements reviewed during the Standard Survey.

Task 5 includes the following subtasks:

- 5A General Observations of the Facility: Assessment of the environment of the facility affecting the resident's life, health and safety;

- 5B Kitchen/Food Service Observations: Assessment of the facility's food storage, preparation and service;

- 5C Resident Review: An integrated, holistic assessment of the sampled residents which includes the assessment of: drug therapies, the quality of life of the resident as affected by his/her room environment and daily interactions with staff, and assessment of those pertinent care concerns identified for each sampled resident by the survey team. Closed record reviews and dining observations are integrated into the resident review;

- 5D Quality of Life Assessment: Assessment of residents' quality of life through individual interviews, a group interview, family interviews, and observations of residents who are non-interviewable;

- 5E Medication Pass Observation: Application of Medication Error Detection Methodology;

- 5F Quality Assessment and Assurance Review: An assessment of the facility's Quality Assessment and Assurance program to determine if the facility identifies and addresses specific care and quality issues and implements a program to resolve those issues; and

- 5G Abuse Prohibition Review: A determination of whether the facility has developed and operationalized policies and procedures designed to protect residents from abuse, neglect, involuntary seclusion, and misappropriation of their property. This includes policies and procedures for hiring practices, training and ongoing supervision for employees and volunteers who provide services, and the reporting and investigation of allegations and occurrences that may indicate abuse.

Use survey worksheets and Guidance to Surveyors (also known as the Interpretive Guidelines) for each of the sub-tasks and requirements reviewed in Task 5. While these sub-tasks are discrete information gathering activities, there are a number of things to take into consideration during Task 5.

A. General Procedures.--As appropriate, use the interpretations, definitions, probes, and procedures provided in the Guidance to Surveyors to guide your investigation and to help determine whether, based on your investigation and findings, the facility has met the requirements.

Worksheet documentation should be resident-centered, as appropriate. For example, if you are documenting the lack of a reading light near the resident's bedroom chair, also note that this resident has told you he prefers to read in his chair, and that the light over the chair is inadequate.

Relate to the requirements and provide clear evidence, as appropriate, of the facility's failure to meet a requirement. As you collect information, keep in mind that the information you write on your

worksheet will be used by the team to decide if there are any deficiencies, and, if so, the degree of severity and scope. Make your documentation specific enough so that these decisions can be made. Include information about how the faulty facility practice affected residents, the number of residents affected, and the number of residents at risk. This documentation will be used both to make deficiency determinations and to categorize deficiencies for severity and scope. The Guidance to Surveyors assists in gathering information in order to determine whether the facility has met the requirements. For example, the facility has care plan objectives which are measurable. If the resident does not meet her/his goals, does your documentation reflect how the lack of implementation of the care plan and/or lack of quarterly assessments prevents the resident from reaching her/his goals?

In conducting the survey, use the worksheets in conjunction with the survey procedures and Guidance to Surveyors when you are investigating a concern, note the tag number listed on the worksheet for that requirement and use the Guidance to Surveyors for that tag to direct your investigation.

Devote as much time as possible during the survey to performing observations and conducting formal and informal interviews. Limit record reviews to obtaining specific information, i.e., look at what you need, not the whole record.

The information gathering tasks are interrelated. Information acquired while doing observations and interviews will direct your record review. Likewise, information obtained while doing the record review may help direct what observations or interviews are needed. Acquire the information that is necessary to make deficiency decisions in Task 6 using the survey worksheets and corresponding Guidance to Surveyors for each of the sub-tasks in
Task 5.

Regardless of the task in which you are engaged, be alert at all times to the care environment and activities around you. For example, while conducting the dining observations of sampled residents and the medication pass observation, observe the environment and residents, e.g., care being given, staff interactions with residents and infection control practices.

The team should meet on a daily basis to share information (e.g., findings to date, areas of concern, any changes needed in the focus of the survey). These meetings include discussions of concerns observed, possible requirements to which those problems relate, and strategies for gathering additional information to determine whether the facility is meeting the requirements.
Throughout the survey, discuss your observations, as appropriate, with team members, facility staff, residents, family members, and the ombudsman. Maintain an open and ongoing dialogue with the facility throughout the survey process. This gives the facility the opportunity to provide you with additional information in considering any alternative explanations before you make deficiency decisions. This, however, does not mean that you report every negative observation on a daily basis, i.e., at a nightly conference. Moreover, if the negative observation relates to a routine that needs to be monitored over time to determine whether a deficiency exists, wait until a trend has been established before notifying the facility of the problem. If you have verified through observation and record review, that a resident's condition has declined, start your investigation to determine if this decline was avoidable or unavoidable by asking a knowledgeable facility staff member, such as the nurse or other professional staff member charged with responsibility for the resident's care to show you documentation in the resident's chart that provides the reasons for why they believe this decline occurred. Use this information to guide your investigation, but use your professional judgment and team approach to determine if a deficient practice has occurred.

In conducting the tasks of the Standard Survey, you may identify situations that lead you to believe that the facility may not be meeting a requirement not routinely reviewed in the Standard Survey.

Investigate this further. For example, residents at the council meeting tell you that they have not had a visit from a physician (or extender) for several months. This would lead to an investigation of facility compliance with the requirements for frequency of physician visits.

Verify your information and observations in terms of credibility and reliability. If you doubt the credibility or reliability of information, validate that information or gather additional information before using it to make a compliance decision.

B. Observations.--The objectives of the observational portion of information gathering are to gather resident-specific information for the residents included in the sample, and also, to be alert to the provision of care, staff-resident interactions, and quality of life for all residents.

C. Informal and Formal Interviews.--The objectives of interviews are to:

- o Collect information;
- o Verify and validate information obtained from other survey procedures; and
- o Provide the opportunity for all interested parties to give you what they believe is pertinent information.

Interview residents, staff, family, ombudsman, family council representatives, and other appropriate persons. Informal interviews are conducted throughout the duration of the information gathering tasks of the survey. Formal structured interviews are also done as part of the Quality of Life Assessment protocols. Use the information obtained from interviews to assist you in deciding what additional observations and record review information is necessary. Avoid asking leading questions, but use the Guidance to Surveyors for specific requirements to focus your questions and determine the significance of the answers.

In general, the individual who provides information during an interview will not be identified as providing that information. However, it is possible that their identity may be revealed if a deficiency is cited based in whole or part on their information, and that deficiency citation is appealed.

If residents appear reticent in providing you with information or express concern about retaliation:

- o Verify that residents have information on whom to contact in the event they become the objects of retaliation by the facility; and
- o Notify the ombudsman of the resident's concerns if you have the resident's permission.

D. Record Review.--The objectives of the record review are to:

- o Acquire information to direct initial and/or additional observations and interviews;
- o Provide you with a picture of the current status of the resident as assessed by the facility; and
- o Evaluate assessments, plans of care, and outcomes of care interventions for residents included in the sample. Record review of RAI information, care planning, implementation of the care plan and evaluation of care is one facet of the resident review which determines if there has been a decline, improvement, or maintenance in identified focus areas.

NOTE: Do not spend excessive time gathering and recording information from the record. Use the record review to obtain information necessary to validate and/or clarify information you have obtained through observation and interviews. Ask facility staff to assist you in finding any information that you have been unable to find on your own or that requires validation.

TASK 5A - GENERAL OBSERVATIONS OF THE FACILITY.

A. General Objective.--The general objective of this task is to observe physical features in the facility's environment that affect residents' quality of life, health, and safety. Use the General Observations of the Facility worksheet (HCFA-803, Exhibit 91) to complete this task.

B. General Procedures.--During the Initial Tour, each surveyor should note and document any concerns in resident rooms and the general environment. Any concerns should be investigated and followed up either through the resident review for sampled residents or during the General Observation task. During the remainder of the survey, one surveyor is assigned to complete the General Observation of the Facility worksheet. This surveyor assures that all items on this worksheet are completed. All surveyors should share any additional concerns regarding the environment with the surveyor assigned to complete the worksheet. Begin your observations as soon as possible after entering the facility, normally after introductions at the entrance conference.

During Task 5A, review the condition of the environment (e.g., cleanliness, sanitation, presence or absence of pests, accident hazards, functioning of equipment, and the proper and safe storage of drugs, biologicals, housekeeping compounds and equipment). (See HCFA-803 worksheet for specific areas to review.)

C. Making Observations.--The focus in Task 5A is on quality of life and environmental health and safety indicators in areas of the facility that would be visited or used by residents. However, some non-resident areas should also be reviewed due to their potential negative effect on residents (e.g., utility rooms).

Document thoroughly at the time you are observing. If additional documentation space is needed, use the Surveyor Notes Worksheet, HCFA-807.

Plan to observe the facility's environment at different times during the survey (e.g., first and second shift, common areas when in use by residents).

Share any concerns with the team coordinator and other team members to determine the possible need to gather additional information.

TASK 5B - KITCHEN/FOOD SERVICE OBSERVATION

A. General Objective.--The general objective of the Kitchen/Food Service Observation is to determine if the facility is storing, preparing, distributing, and serving food according to 42 CFR 483.35(h)(2) to prevent food borne illness.

B. General Procedures.--One surveyor is assigned to conduct the Kitchen/Food service observation.

NOTE: The surveyor assigned to complete this task should begin the task with a brief visit to the kitchen as part of the initial tour, in order to observe the sanitation practices and cleanliness of the kitchen. Observe whether potentially hazardous foods have been left on counter tops or steam table and/or being prepared, the manner in which foods are being thawed, the cleanliness, sanitary practices, and appearance of kitchen staff (e.g., appropriate attire, hair restraints).

Use the Kitchen/Food Service Observation worksheet to direct your observations of food storage,food preparation, and food service/sanitation. (See Kitchen/Food Service Observation worksheet (HCFA-804, Exhibit 92) for specific areas to review).

In addition to completion of the HCFA-804, also evaluate:

- The availability of food in relation to the number of residents;
- Whether food being prepared is consistent with the written, planned menu.

NOTE: During team meetings, if surveyors, during the Dining Observation portion of the Resident Review, identified any concerns, such as the provision of meals that are not consistent in quality (such as color and texture of vegetables or meats, the preparation and presentation of mechanically altered foods); complaints regarding taste or texture of food and foods with an "off" or bad odor; or residents being at nutritional risk, including high prevalence of residents with unintended weight loss; then the surveyor assigned to Task 5(b) should review the following as appropriate.

Direct observations to the tray line and kitchen to determine:

- If recipes are available and consistent with the menu and followed by employees;
- If appropriate equipment is available and used to prepare and serve foods;
- If the food is being held for more than thirty minutes prior to food service, e.g., in the steam table, oven, refrigerator rather than freezer for frozen foods, etc.; and
- If cooked leftovers used during food preparation were stored and used within the appropriate time frames, and reheated to at least 165 degrees F.

TASK 5C - RESIDENT REVIEW

A. General Objectives.--The general objectives of the Resident Review are to determine:

- How resident outcomes and the resident's quality of life are related to the provision of care by the facility;
- If the care provided by the facility has enabled residents to reach or maintain their highest practicable physical, mental, and psychosocial well-being;
- If residents are assisted to have the best quality of life that is possible. Your review will include aspects of the environment, staff interactions, and provision of services that affect sampled residents in their daily lives;

o If the facility has properly assessed its residents through the completion of the Resident Assessment Instrument (RAI), including accurate coding and transmitting of the Minimum Data Set (MDS) and has properly assessed care needs, conducted proper care planning, implemented the plan and evaluated care provided to the residents; and

o If there are additional areas of concern that need to be investigated in Phase II of the survey.

B. General Procedures.-- The team coordinator assigns specific residents in the sample to surveyors.

One surveyor should conduct the entire Resident Review for an assigned resident. If the resident has been chosen for a Quality of Life Assessment protocol (Task 5D), this same surveyor should also complete that protocol. If a surveyor has not passed both sections of the Surveyor Minimum Qualifications Test (SMQT) or if the complexity of a resident's care requires expertise of more than one discipline, two surveyors should work jointly to complete the review. A surveyor must successfully complete Module B of the SMQT to survey independently the requirements of quality of care, clinical dietary and medication.

To facilitate the Resident Review, ask the charge nurse for schedules of the following, as appropriate:

1. Meals;
2. Medications;
3. Activities;
4. Tube feedings and special treatments;
5. Specialized rehabilitation therapies; and
6. Physician visits or visits of other health professionals such as dentists, podiatrists, or nurse practitioners.

For all sampled residents except closed records, parts A, B, and C (Resident Room Review, Daily Life Review, Assessment of Drug Therapies) on the Resident Review Worksheet (Exhibit 93) are completed. The difference between the two reviews is that the focus of the part D Care Review is more extensive for Comprehensive Reviews. Determine, as appropriate, if there has been a decline, maintenance or improvement of the resident in the identified focused care areas and/or Activities of Daily Living (ADL) functioning. If there has been a lack of improvement or a decline, determine if the decline or lack of improvement was avoidable or unavoidable.

C. Comprehensive Care Review.--A Comprehensive Review includes observations, interviews, and a record review. After observing and talking with the resident, the surveyor conducts a comprehensive review which includes the following:

o A check of specific items on the MDS for accurate coding of the resident's condition. The specific items to be checked will be based on QIs identified for the resident on the Resident Level Summary. At least 2 of the QIs identified for the resident must be matched against the QI definitions (see the QI definition matrix, Exhibit 270) and against evidence other than the MDS to verify that the resident's condition is accurately recorded in the MDS. Keep in mind that you are verifying that the resident's condition was accurately assessed at the time the MDS was completed;

o An overall review of the facility's completion of the RAI process including their:

- Use of the Resident Assessment Protocols (RAPs);

- Evaluation of assessment information not covered by the RAPs;

- Identification of risks and causes of resident conditions;

- Completion of the RAP Summary;

- Development of a care plan that meets the identified needs of the resident;

o A review of the implementation of the care plan and resident response;

o A review of the relationship of the resident's drug regimen to the resident's condition (see the description of procedures for completing part C below);

o A thorough review of any of the following conditions that apply to the resident: weight loss, dehydration, pressure sores. This review is completed using the investigative protocols found below as a guide. (NOTE: All the residents selected for comprehensive reviews should have one or more of these concerns checked on the QI reports [unless there are no residents with these concerns in the facility.]); and

o An evaluation of the resident's dining experience (see Dining Observation Protocol below).

D. Focused Care Review Phase 1.--This focused review includes observations, interviews, and a record review. This review focuses on care areas that were checked for the resident on the Resident Level Summary and any additional care items checked by the team as pertinent to the resident. (That is, all areas that are checked on the Roster/Sample Matrix by the team for the resident are reviewed, whether or not they have been highlighted as concerns for the survey.) The dining observation is done for a resident if the resident has any checkmarks related to dining or the investigating team member has any concerns about the resident related to dining (such as weight loss).

The Phase 1 focused care review includes all care areas the team has checked for the resident: a review of the MDS, the facility's use of the RAPs, care planning, implementation of the care plan, and the resident's response to the care provided.

E. Focused Care Review Phase 2.--This focused review includes observations, interviews and a record review which concentrates only on those areas of concern for which the team requires additional information. For example, if the team needs additional information concerning facility compliance with the requirements for tube feeding, review only those RAI areas related to tube feeding; make observations of nutritional status, complications, and techniques of tube feeding, and interview residents, family and staff concerning related areas.

F. Closed Record Review.--This includes a record review of the resident's care issues and transfer and discharge requirements. It may be possible to select some or all of the closed records from the preselected list of residents for the Phase 1 sample, if any of these preselected residents were noted onsite to be discharged or deceased.

Assess quality of care and quality of life requirements that relate to the identified care areas for the sampled resident. While assessing these, note and investigate concerns with any other requirements.

G. Conducting the Resident Review.--The Resident Review consists of 4 main sections: Resident Room Review, Daily Life Review, Assessment of Drug Therapies, and Care Review. See Resident Review Worksheet and instructions (HCFA-805, Exhibit 93) for specific areas to review.

1. Section A.--The Resident Room Review assesses aspects of accommodation of needs, environmental quality, and quality of life in the resident's room. Evaluate through your observations and interviews how the resident's environment affects her/his quality of life.

2. Section B.--The Daily Life Review is a review of the resident's daily quality of life, especially in the areas of staff responsiveness to resident grooming and other needs, staff interactions, choices, and activities. Through your ongoing observations and interviews, evaluate the resident's daily life routines and interactions with staff.

3. Section C.--The assessment of drug therapies is a review of the medications the resident is receiving to evaluate whether the effectiveness of the therapeutic regimen (including all drugs that may play a significant role in the resident's everyday life) is being monitored and assessed.

General Procedures:

Conduct an assessment of drug therapies for residents selected for comprehensive and focused review. (In addition, if the team has identified a concern that relates to the medication regimen, include a review of medication regimen in closed record reviews).

o Record the information on the Resident Review Worksheet, HCFA 805. Review and record, as pertinent, all non prescription and prescription medications taken by the resident during the past 7 days.

o Evaluate for the presence of any unnecessary drugs. (Review of the unnecessary drug requirements includes drugs and protocols or circumstances described in all sections of 42 CFR 483.25(l). and as pertinent, 42 CFR 483.60(c)(2).) The surveyor is to review the medication regimen for the following:

- Indications/reason for use;

- Effectiveness of therapeutic goal;

- Dose;

- Presence of monitoring (including drug regimen review and response to identified irregularities);

- Presence of duplicative therapy; and

- Presence of possible Adverse Drug Reactions (ADR) or side effects. In addition, review for the presence of any medications with "High Potential for Severe ADRs" or "High Potential for Less Severe ADRs" as identified in the Guidance to Surveyors. (If any of these medications are identified, use the "Investigative Protocol: Adverse Drug Reactions" below).

NOTE: An ADR is a secondary effect of a drug that is usually undesirable and different from the therapeutic and helpful effects of the drug. The term "side effect" is often used interchangeably with ADR. Technically, however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse drug interactions. Formal definitions stress an ADR is any response to a drug that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis or therapy.

o Correlate the review of the drugs with the resident's clinical condition and any extenuating circumstances, such as recent admission, a change in the resident's environment, and hospitalization, etc.

o Evaluate how the drugs the resident receives affect her/his quality of care and quality of life through the following methods:

- A review of the clinical record (i.e., any section that has useful information pertaining to the resident);

- Observations of the resident; and

- Interviews with the resident or interested parties.

o Allow the facility the opportunity to provide their rationale for use of drugs which are prescribed contrary to HCFA guidelines.

o If problems or concerns with drug therapy are noted, review the results of the pharmacist's drug regimen review, and the response from the attending physician/director of nurses. (The Medical Director may have provided additional information regarding the specific issues identified during the resident's medication review.)

Use the following investigative protocol for the review of apparent adverse drug reaction.

INVESTIGATIVE PROTOCOL:

ADVERSE DRUG REACTIONS (ADR)

Objectives:

o To determine if the resident may be experiencing any ADRs as a result of receiving one or more of the medications identified with high potential for severe ADRs or high potential for less severe ADRs.

o To determine whether the facility's drug regimen review process identified and reported any potential irregularities associated with the use of medications listed as having a high potential for ADRs, and whether there was any response to this notification.

Task 5C: Use:

Use this protocol if the resident meets the following criteria:

o Is over 65 years old;

o Has been in the facility over 7 days (or appears to be having a noticeable ADR within the first 7 days); and

o Is receiving any of the medications which has a high potential for severe ADRs or a high potential for less severe ADRs at 42 CFR 483.25(l) and 42 CFR 483.60(c)(2) in the guidance to surveyors, respectively.

NOTE: An Adverse Drug Reaction (ADR) is a secondary effect of a drug that is usually undesirable and different from the therapeutic and helpful effects of the drug. The term "side effect" is often used interchangeably with ADR. Technically, however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse drug interactions. An ADR is any response to a drug that is noxious and unintended and occurs in doses for prophylaxis, diagnosis or therapy.

Procedures:

These procedures are not intended to instruct surveyors to determine if a resident outcome is an actual ADR (except in obvious circumstances), but are guidelines intended to guide surveyors to find the pertinent facts that will assist them in determining compliance. In addition, the list of drugs and adverse reactions in the guidelines are not all inclusive and other medication sources may be reviewed for evaluation of the drug regimen.

1. Screening.-- If the criteria for use of the protocol are met, use the following (additional resources may be used, e.g., information provided by the facility, journals, etc.) to identify whether the resident may be experiencing a potential ADR.

o Review of Drugs With High Potential for Severe ADRs.--For this review, refer to the drugs and the Adverse Drug Reactions found in the surveyor guidance at 42 CFR 483.25(l), Section H, Unnecessary Drugs.

- Determine if there is evidence in the record explaining why the benefit of this medication outweighs the risk of a potential ADR, that is, the facility notes indicate the reasons that the medication is the one of choice for a particular resident.

- Determine if the resident is experiencing decline or other negative outcome as a result of the apparent ADR.

o Review of Drugs With High Potential For Less-Severe ADRs.--For this review, refer to the list of drugs in the surveyor guidance at F429, Drug Regimen Review.

- Determine if there is evidence in the record explaining why the benefit of this medication outweighs the risk of a potential ADR, that is, the facility notes indicate the reasons that the medication is the one of choice for a particular resident.

2. Analyze.--Base evidence that an apparent ADR occurred or is occurring on two sources of information (clinical record review, interview with the resident or interested party, and observation, or one source for closed records).

3. Review Facility Response.--If the resident is experiencing any potential ADR, determine whether the facility has identified and addressed/acknowledged the potential ADR.

4. Additional Considerations.--When conducting the review, consider the following:

o The use of any medication that appears in the Guidance to Surveyors at 42 CFR 483.25(l) and 42 CFR 483.60(c)(2) could be an appropriate therapy, if valid documentation supporting its use is provided;

o The prescribing of medication should always take into consideration its risks and benefits (e.g., the benefits of a pain medication versus the risk of worsened constipation in a person already prone to constipation);

o The side effects of many medications are similar or the same as for other medications or disease processes; and

o In some cases, the benefits of a particular medication may not be self-evident, and additional pertinent information (either written or verbal) should be requested from the facility.

o This protocol does not supercede current regulation. The surveyor has the option to cite at F329 (Unnecessary Drugs) or F429 (Drug Regimen Review) based on the situation.

Task 6: Determination of Compliance:

o Compliance with 42 CFR 483.25(l)(1)(i-vi), of F329: Unnecessary Drugs.

- For this resident, the medication is not an unnecessary drug if the facility: identified the risks; determined that the benefit of this drug outweighs the risk or development of a potential ADR, that is, the facility indicates the reasons that the drug is the one of choice for a particular resident; and the facility continually assessed the use of the drug and determined that this continued to be a valid therapeutic intervention for the resident. If not, the medication is an unnecessary drug-- Cite F329.

o Compliance with 42 CFR 483.60(c)(2), F429, Drug Regimen Review:

- For this resident, the drug regimen review is in compliance if the facility identified the risks, assessed, and determined if the benefit of this drug outweighs the risk of a potential ADR, that is, the facility notes indicate the reasons for the drug is the one of choice for a particular resident. If the facility has not completed the above review and assessment, but the pharmacist has identified and reported the apparent irregularity to the attending physician/director of nursing as part of the drug regimen review process, the drug regimen review is in compliance. If not--Cite F429.

4. Section D.--The care review is an assessment of those quality of care areas (see 42 CFR 483.25) that are pertinent to the sampled resident. The survey team, through use of the Roster/Sample Matrix, determines what care areas will be reviewed for each sampled resident. (Additional areas for evaluation may be identified during the review.)

There are a designated number of comprehensive, focused and closed record care reviews completed, depending on the size of the sample.

H. Care Observations and Interviews.--Make resident observations and conduct interviews which include those factors or care areas as determined by the Roster/Sample Matrix. For example, if the resident was chosen because she/he is receiving tube feedings, observe the care and the outcomes of the interventions, facility monitoring and assessment, and nutritional needs/adequacy related to tube feeding.

Complete the following tasks:

o Observe the resident and care givers during care and treatments, at meals, and various times of the day (including early morning and evening) over the entire survey period. Observe residents in both informal and structured settings, e.g., receiving specialized rehabilitation services, participating in formal and informal activities. Also, observe staff-resident interactions;

o Gather resident-specific information, including information on the resident's functional ability, potential for increasing ability, and any complications concerning special care needs;

o Evaluate implementation of the care plan. Determine if the care plan is consistently implemented by all personnel at all times of the day, and if the care plan is working for the resident. If the care plan is not working, look for evidence that the facility has identified this and acted on it even if the care plan has not formally been revised;

o Determine if there is a significant difference between the facility's assessment of the resident and your observations; and

o Evaluate the adequacy of care provided to the resident using the Guidance to Surveyors.

Do not continue to follow residents once you have accrued enough information to determine whether the resident has received care in accordance with the regulatory requirements.

If there are indicators to suggest the presence of a quality of care problem that is not readily observable, (e.g., a leg ulcer covered with a dressing, or a sacral pressure sore), ask facility staff to assist you in making your observations by removing, for example, a dressing or bedclothes.

Resident care observations should be made by those persons who have the clinical knowledge and skills to evaluate compliance.

When observing residents, respect their right to privacy, including the privacy of their bodies. If you must observe the resident's genital or rectal area or female breast area to document and confirm your suspicions of a care problem, a member of the nursing staff must be present at this observation, and the resident must give clear consent.

If the resident is unable to give consent (e.g., is unresponsive, incompetent), and a legal surrogate (family member who can act on the resident's behalf or legal representative as provided by State law) is present, ask this individual to give consent.

You may make an observation of a resident's rectal or genital area (and for females, the breast area) without a resident's or legal surrogate's consent, under the following conditions:

1. You determine that there is a strong possibility that the resident is receiving less than adequate care which can only be confirmed by direct observation;

2. The resident is unable to give clear consent; and

3. A legal surrogate is not present in the facility.

Only a surveyor who is a licensed nurse, a physician's assistant or a physician may make an observation of a resident's genitals, rectal area, or, for females, the breast area.

I. Record Review.--Conduct a record review to provide a picture of the current status of the resident as assessed by the facility; information on changes in the resident's status over the last 12 months for those areas identified for review; and information on planned care, resident goals, and expected outcomes.

Use the record review to help determine whether the assessments accurately reflect the resident's status and are internally consistent. An example of inconsistency may be that the facility assessed the resident's ADLs as being independently performed yet had indicated that the resident requires task segmentation for performing ADLs.

For sampled residents selected for either a comprehensive or focused review, conduct a review of the RAI information including:

- The face sheet of the MDS for background information including customary routines and demographic information to provide an understanding of the resident prior to admission. This assists in assessing the quality of life of the resident.

- The latest MDS to determine which RAPS were triggered. For a sampled resident receiving a comprehensive review, note all triggered areas. Also, review the facility's assessment of the resident's level of functioning and note particularly drug therapy and cognitive, behavior, and ADL function. For a resident receiving a focused review in Phase I of the survey, review both the areas of concern specific to the resident and the other care areas that have been identified with the Roster/Sample Matrix. For Phase 2 residents, review only those areas that have been identified by the team as areas of concern.

If the RAI is less than 9 months old, review and compare with the previous RAI and the most recent quarterly review. If the RAI is 9 months or older, compare the current RAI with the most recent quarterly review. Review the following:

- The RAP summary sheet to see where the assessment documentation is located for any RAP triggered;

- The information summarizing the assessments (RAPS) and decision to proceed or not to proceed to care planning. Determine if the assessments indicate that the facility used the RAPs and considered the nature of the problem, the causal and risk factors, the need for referrals, complications, and decisions for care planning. If this is a reassessment, review whether the facility determined if the care plan required revision or was effective in moving the resident toward his/her goals;

o The care plan to identify whether the facility used the RAI to make sound care planning decisions. Determine whether the facility identified resident strengths, needs, and problems which needed to be addressed to assist the resident to maintain or improve his/her current functional status. Determine whether the facility identified resident-centered, measurable goals and specific interventions to achieve those goals. With observations, interviews, and record review, determine if the facility implemented the interventions defined; and

o Determine whether the facility documentation and resident status as observed indicate the decision to proceed or not to proceed to care planning was appropriate. This information will assist in determining whether a resident's decline or failure to improve was avoidable or unavoidable.

It is not necessary to review the entire resident record. Review only those sections that are necessary to verify and clarify the information necessary to make compliance decisions. These sections may include, for example, laboratory reports, progress notes, and drug regimen review reports.

In any care area in which you determine that there has been a lack of improvement, a decline, or failure to reach highest practicable well being, assess if the change for the resident was avoidable or unavoidable. Note both the faulty facility practice and its effect on resident(s). Determine if a reassessment based on significant change should have been conducted, and if the absence of reassessment contributed to the resident's decline or lack of improvement.

o Verify that you have the information needed to determine if the facility fulfilled its obligation to provide care that allowed the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being.

NOTE: WHEN CONDUCTING EITHER A FOCUSED OR COMPREHENSIVE REVIEW, IF THERE ARE AREAS OF CONCERN WHICH FALL OUTSIDE THE CARE AREAS IDENTIFIED, YOU MUST INVESTIGATE THESE, AS NECESSARY.

The following are special investigative protocols which should be used in Task 5C to gather information and in Task 6, to determine facility compliance in the care areas of pressure sore/ulcer(s), hydration, unintended weight loss, sufficient nursing staffing, and dining and food services.

NOTE: "Although the RAI assessments discussed in the following [investigative protocols] must occur at specific times, by Federal regulation, a facility's obligation to meet each resident's needs through ongoing assessment is not neatly confined to these mandated time frames. Likewise, completion of the RAI in the prescribed time frame does not necessarily fulfill a facility's obligation to perform a comprehensive assessment. Facility's are responsible for assessing areas that are relevant to individual residents regardless of whether these areas are included in the RAI." (HCFA Long Term Care Resident Assessment Instrument User's Manual, Version 2.0, 10/95.)

INVESTIGATIVE PROTOCOL

PRESSURE SORE/ULCER

Objectives:

o To determine if the identified pressure sore/ulcer(s) is avoidable or unavoidable; and

o To determine the adequacy of the facility's pressure sore/ulcer treatment and prevention interventions.

Task 5C: Use:

Utilize this protocol for a sampled resident who has been selected as having a pressure sore/ulcer from either the high or low risk group as shown on the Resident Level Summary Report.

NOTE: The Facility QI Profile will flag a sentinel event if the development of a pressure sore/ulcer occurred for a person who was at low risk. To identify the resident, refer to the Resident Level Summary, QI #24, Pressure Ulcer, Low Risk column.

Procedures:

o Observations/interviews conducted as part of this procedure should be recorded on the HCFA-805.

o Conduct a brief review of the assessment and care plan noting the facility's interventions.

o Observe care delivery to determine if the interventions identified in the care plan have been implemented, such as incontinence care with frequency to keep the resident clean and skin dry, repositioning and evaluation of skin condition, nutritional interventions, treatment interventions and changes in skin condition and healing.

NOTE: The development of a pressure sore/ulcer may not have triggered a significant change RAI. In addition, if the pressure sore/ulcer has just developed, the facility may be in the process of assessment. Regardless of the timing of the assessment, the facility is required to develop and implement a care plan to meet the needs of the resident

o Evaluate if the assessment that was conducted identified conditions that may put the resident at risk for development of a pressure sore/ulcer such as the following:

- Diabetes, peripheral vascular disease, chronic obstructive pulmonary disease, a terminal condition, hip fractures or other surgical interventions which might limit mobility, cerebral vascular accident; immobility, hemiplegia/hemiparesis, physical restraints, decreased sensory perception, history of a pressure sore, incontinence, edema, compromised nutritional status, such as unintended weight loss, or malnutrition. (Also see Guidance to Surveyors at F314 for additional examples.)

o Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident's condition or problem.

o Determine if the facility developed a care plan with interventions for the prevention of the development of a pressure sore/ulcer for a resident who was identified at risk for the development of a pressure sore/ulcer. Determine if the facility maintained an ongoing evaluation of their interventions to evaluate the effectiveness of their approaches, with revision of the care plan, as needed. The identification of risk factors and/or clinical conditions does not necessarily indicate that a pressure sore/ulcer development was unavoidable. The facility must continue to evaluate the interventions and implementation of the care plan.

o Determine for a resident who was at low risk for development of a pressure sore/ulcer, whether the facility identified, assessed and intervened to address the changes which contributed to the development of the pressure sore/ulcer. For example, an ambulatory resident who developed a heel ulcer from an ill fitting shoe or an ulcer/sore which developed from pressure from clothing, such as support hosiery, or pressure from medical devices.)

o For a resident who was admitted with a pressure sore/ulcer, determine if an interdisciplinary care plan was developed for the conditions identified. Are care plan interventions, such as pressure relieving devices, nutritional interventions and other measures, developed to provide an aggressive program of prevention and/or treatment?

o Determine if the care plan is consistently implemented, evaluated and revised based on the response, outcomes, and needs of the resident.

o Determine if the resident refused treatment (for example, refusing to be positioned off the affected side). If this situation occurred, did the facility counsel the resident about possible alternatives and consequences, if appropriate? Did the facility reevaluate and attempt other interventions?

Task 6: Determination of Compliance:

o Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sores:

- For this resident, the pressure sore/ulcer is unavoidable if the facility properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, the pressure sore/ulcer is avoidable; cite at F314.

o Compliance with 483.25(c)(2), F314, Pressure Sore Treatment:

- For this resident, the facility is compliant with the portion of this requirement dealing with treatment of existing pressure sore/ulcer(s) if the facility provided appropriate care planning and treatment, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F314.

o Compliance with 42 CFR 483.20(b)(1), F272, Comprehensive Assessments:

- For this resident in the area of pressure sore/ulcer(s), the facility is compliant with this requirement if they assessed factors that put the resident at risk for the development of a pressure sore/ulcer. If not, cite at F272.

o Compliance with 42 CFR 483.20(k), F279, Comprehensive Care Plans:

- For this resident in the area of pressure sore/ulcer(s), the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident's needs as identified in the resident's assessment. If not, cite at F279.

o Compliance with 42 CFR 483.20(k)(3)(ii), F282, Provision of Care in Accordance with the Care Plan:

- For this resident in the area of pressure sore/ulcer(s), the facility is compliant with this requirement if qualified persons implemented the resident's care plan. If not, cite at F282.

INVESTIGATIVE PROTOCOL

HYDRATION

Objectives:

o To determine if the facility identified risk factors which lead to dehydration and developed an appropriate preventative care plan; and

o To determine if the facility provided the resident with sufficient fluid intake to maintain proper hydration and health.

Task 5C: Use:

Use this protocol for the following situations:

o A sampled resident who flagged for the sentinel event of dehydration on the Resident Level Summary;

o A sampled resident who has one or more QI conditions identified on the Resident Level Summary, such as;

- #11 - Fecal impaction;
- #12 - Urinary tract infections;
- #13 - Weight loss;
- #14 - Tube feeding;
- #17 - Decline in ADLs;
- #24 - Pressure Ulcer

o A sampled resident who was discovered to have any of the following risk factors: vomiting/diarrhea resulting in fluid loss, elevated temperatures and/or infectious processes, dependence on staff for the provision of fluid intake, use of medications including diuretics, laxatives, and cardiovascular agents, renal disease, dysphagia, a history of refusing fluids, limited fluid intake or lacking the sensation of thirst.

Procedures:

o Observations/interviews conducted as part of this procedure should be recorded on the HCFA-805 and/or the HCFA-807.

o Determine if the resident was assessed to identify risk factors that can lead to dehydration, such as those listed above and also whether there were abnormal laboratory test values which may be an indicator of dehydration.

NOTE: A general guideline for determining baseline daily fluid needs is to multiply the resident's body weight in kilograms (kg) x 30ml (2.2 lbs = 1 kg), except for residents with renal or cardiac distress, or other restrictions based on physician orders. An excess of fluids can be detrimental for these residents.

o Determine if an interdisciplinary care plan was developed utilizing the clinical conditions and risk factors identified, taking into account the amount of fluid that the resident requires. If the

resident is receiving enteral nutritional support, determine if the tube feeding orders included a sufficient amount of free water, and whether the water and feeding are being administered in accordance with physician orders?

o Observe the care delivery to determine if the interventions identified in the care plan have been implemented as described.

- What is the resident's response to the interventions? Do staff provide the necessary fluids as described in the plan? (Do the fluids provided contribute to dehydration, for example, caffeinated beverages, alcohol?) Was the correct type of fluid provided with a resident with dysphagia?

- Is the resident able to reach, pour and drink fluids without assistance and is the resident consuming sufficient fluids? If not, are staff providing the fluids according to the care plan?

- Is the resident's room temperature (heating mechanism) contributing to dehydration? If so, how is the facility addressing this issue?

- If the resident refuses water, are alternative fluids offered that are tolerable to the resident?

- Are the resident's beverage preferences identified and honored at meals?

- Do staff encourage the resident to drink? Are they aware of the resident's fluid needs? Are staff providing fluids during and between meals?

- Determine how the facility monitors to assure that the resident maintains fluid parameters as planned. If the facility is monitoring the intake and output of the resident, review the record to determine if the fluid goals or calculated fluid needs were met consistently.

o Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident's condition or problem.

NOTE: If a resident is at an end of life stage and has an advance directive, according to State law, (or a decision has been made by the resident's surrogate or representative, in accordance with State law) or the resident has reached an end of life stage in which minimal amounts of fluids are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then dehydration may be an expected outcome and does not constitute non-compliance with the requirement for hydration. Conduct observations to verify that palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident's comfort and quality of life. If the facility has failed to provide the palliative care, cite non-compliance with 42 CFR 483.25, F309, Quality of Care.

o Determine if the care plan is evaluated and revised based on the response, outcomes, and needs of the resident.

Task 6: Determination of Compliance:

o Compliance with 42 CFR 483.25(j), F327, Hydration:

- For this resident, the facility is compliant with this requirement to maintain proper hydration if they properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F327.

o Compliance with 42 CFR 483.20(b)(1) & (2), F272, Comprehensive Assessments:

- For this resident in the area of hydration, the facility is compliant with this requirement if they assessed factors that put the resident at risk for dehydration, whether chronic or acute. If not, cite at F272.

o Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:

- For this resident in the area of hydration, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident's needs as identified in the resident's assessment. If not, cite at F279.

o Compliance with 483.20(k)(3)(ii), F 282, Provision of care in accordance with the care plan:

- For this resident in the area of hydration, the facility is compliant with this requirement if qualified persons implemented the resident's care plan. If not, cite at F282.

Next Page is P-45

INVESTIGATIVE PROTOCOL

UNINTENDED WEIGHT LOSS

Objectives:

- o To determine if the identified weight loss is avoidable or unavoidable; and
- o To determine the adequacy of the facility's response to the weight loss.

Task 5C: Use:

Utilize this protocol for a sampled resident with unintended weight loss.

Procedures:

o Observations/interviews conducted as part of this procedure should be recorded on the HCFA-805 if they pertain to a specific sampled resident and on the HCFA-807 if they relate to general observations of the dining service/dining room.

o Determine if the resident was assessed for conditions that may have put the resident at risk for unintended weight loss such as the following:

- Cancer, renal disease, diabetes, depression, chronic obstructive pulmonary disease, Parkinson's disease, Alzheimer's disease, malnutrition, infection, dehydration, constipation, diarrhea, Body Mass Index (BMI) below 19, dysphagia, chewing and swallowing problems, edentulous, ill fitting dentures, mouth pain, taste/sensory changes, bedfast, totally dependent for eating, pressure ulcer, abnormal laboratory values (review in accordance with the facility's laboratory norms) associated with malnutrition (serum albumin, plasma transferrin, magnesium, hct/hgb, BUN/creatinine ratio, potassium, cholesterol), and use of medications such as diuretics, laxatives, and cardiovascular agents.

NOTE: Amputation of a body part will contribute to a significant decrease in previously targeted weight range. Once the new weight goals are established the resident should be assessed within the parameters of the unintended weight loss investigative protocol.

NOTE: Body Mass Index (BMI) estimates total body mass and is highly correlated with the amount of body fat. It provides important information about body composition, making it a useful indicator of nutritional status. BMI is easy to calculate because only information about height and weight are needed.

BMI = weight (Kg)/height (M^2) or

BMI = weight (lbs.)/height ($inches^2$) X 705

o Determine if the facility has assessed the resident's nutritive and fluid requirements, dining assistance needs, such as assistive devices, food cultural/religious preferences, food allergies, and frequency of meals.

o Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident should know of, or be able to provide information about the causes of a resident's condition or problem.

o Determine if the care plan was developed utilizing the clinical conditions and risk factors identified in the assessment for unintended weight loss. Were the care plan interventions, such as oral supplements, enteral feeding, alternative eating schedule, liberalized diet, nutrient supplements, adaptive utensils, assistance and/or increased time to eat developed to provide an aggressive program of consistent intervention by all appropriate staff?

o Determine if the care plan was evaluated and revised based on the response, outcomes, and needs of the resident.

NOTE: If a resident is at an end of life stage and has an advance directive according to State law, (or a decision has been made by the resident's surrogate or representative in accordance with State law) or the resident has reached an end of life stage in which minimal amounts of nutrients are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then the weight loss may be an expected outcome and may not constitute non-compliance with the requirement for maintaining nutritional parameters. Conduct observations to verify that palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident's comfort and quality of life. If the facility has failed to provide the palliative care, cite non-compliance with 42 CFR 483.25, F309, Quality of Care.

o Observe the delivery of care as described in the care plan (such as staff providing assistance and/or encouragement during dining; serving food as planned with attention to portion sizes, preferences, nutritional supplements, and/or between-meal snacks) to determine if the interventions identified in the care plan have been implemented. Use the Dining and Food Service Investigative Protocol to make this determination.

Task 6: Determination of Compliance:

o Compliance with 42 CFR 483.25 (I), F325, Nutrition

- For this resident, the unintended weight loss is unavoidable if the facility properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, the weight loss is avoidable; cite at F325.

o Compliance with 42 CFR 483.25, F309, Quality of Care:

- For the resident who is in an end-of-life stage and palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident's comfort and quality of life, then for this resident, in the area of palliative care, the facility is compliant with this requirement. If not, cite F309.

o Compliance with 42 CFR 483.20(b)(1) and (2), F272, Comprehensive Assessments:

- For this resident in the area of unintended weight loss, the facility is compliant with this requirement if they assessed the factors that put the resident at risk for weight loss. If not, cite at F272.

o Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:

- For this resident in the area of unintended weight loss, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the residents needs as identified in the resident's assessment. If not, cite at F279.

o Compliance with 42 CFR 483.20(k)(3)(ii), F 282, Provision of care in accordance with the care plan:

- For this resident in the area of unintended weight loss, the facility is compliant with this requirement if qualified persons implemented the resident's care plan. If not, cite at F282.

INVESTIGATIVE PROTOCOL

DINING AND FOOD SERVICE

Objectives:

o To determine if each resident is provided with nourishing, palatable, attractive meals that meet the resident's daily nutritional and special dietary needs;

o To determine if each resident is provided services to maintain or improve eating skills; and

o To determine if the dining experience enhances the resident's quality of life and is supportive of the resident's needs, including food service and staff support during dining.

Use :

This protocol will be used for:

o All sampled residents identified with malnutrition, unintended weight loss, mechanically altered diet, pressure sores/ulcers, and hydration concerns; and

o Food complaints received from residents, families and others.

General Considerations:

o Use this protocol at two meals during the survey, preferably the noon and evening meals.

o Record information on the HCFA-805 if it pertains to a specific sampled resident, or on the HCFA-807 if it relates to the general observations of the dining service/dining room.

- Discretely observe all residents, including sampled residents, during meals keeping questions to a minimum to prevent disruption in the meal service.

o Identify for each sampled resident being observed, any special needs and the interventions planned to meet their needs. Using the facility's menu, record what is planned in writing to be served to the resident at the meal observed.

o Conduct observations of food preparation and quality of meals.

Procedures:

1. During the meal service, observe the dining room and/or resident's room for the following:

   o Comfortable sound levels;

   o Adequate illumination, furnishings, ventilation; absence of odors; and sufficient space;

   o Tables adjusted to accommodate wheelchairs, etc.; and

   o Appropriate hygiene provided prior to meals.

2. Observe whether each resident is properly prepared for meals, for example;

o Resident's eyeglasses, dentures, and/or hearing aids are in place;

o Proper positioning in chair, wheelchair, gerichair, etc. at an appropriate distance from the table (tray table and bed at appropriate height and position); and

o Assistive devices/utensils identified in care plans provided and used as planned.

3. Observe the food service for:

o Appropriateness of dishes and flatware for each resident. (Single use disposable dining ware is not used except in an emergency and, other appropriate dining activities.) Each resident (except those with fluid restriction) has an appropriate place setting with water and napkin;

o Whether meals are attractive, palatable, served at appropriate temperatures and are delivered to residents in a timely fashion.

- Did the meals arrive 30 minutes or more past the scheduled meal time?

- If a substitute was needed, did it arrive more than 15 minutes after the request for a substitute?

o Are diet cards, portion sizes, preferences, and condiment requests being honored?

4. Determine whether residents are being promptly assisted to eat or provided necessary assistance/cueing in a timely manner after their meal is served.

o Note whether residents at the same table (or in resident room's) are being served and assisted concurrently.

5. Determine if the meals served were palatable, attractive, nutritious and met the needs of the resident. Note the following:

o Whether the resident voiced concerns regarding the taste, temperature, quality, quantity and appearance of the meal served;

o Whether mechanically altered diets, such as pureed, were prepared and served as separate entree items (except when combined food: such as stews, casseroles, etc.);

o Whether attempts to determine the reason(s) for the refusal and a substitute of equal nutritive value was provided, if the resident refused/rejected food served; and

o Whether food placement, colors, and textures were in keeping with the resident's needs or deficits (e.g., residents with vision or swallowing deficits).

Sample Tray Procedure

If residents complain about the palatability/temperature of food served, the survey team coordinator may request a test meal to obtain quantitative data to assess the complaints. Send the meal to the unit that is the greatest distance from the kitchen or to the affected unit or dining room. Check food temperature and palatability of the test meal at about the time the last resident on the unit is served and begins eating.

6. Observe for institutional medication pass practices that interfere with the quality of the residents' dining experience. This does not prohibit the administration of medications during meal service for medications that are necessary to be given at a meal, nor does this prohibit a medication to be given during a meal upon request of a resident who is accustomed to taking the medication with the meal, as long as it has been determined that this practice does not interfere with the effectiveness of the medication.

o Has the facility attempted to provide medications at times and in a manner to support the dining experience of the resident, such as:

- Pain medications being given prior to meals so that meals could be eaten in comfort;

- Foods served are not routinely or unnecessarily used as a vehicle to administer medications (mixing the medications with potatoes or other entrees).

7. Determine if the sampled resident consumed adequate amounts of food as planned.

o Determine if the facility is monitoring the foods/fluids consumed. You may use procedures used by the facility to determine percentage of food consumed, if available, otherwise , determine the percentage of food consumed using the following point system:

- Each food item served except for water, coffee, tea, or condiments equals one point. Example: Breakfast: juice, cereal, milk, bread and butter, coffee (no points) equals four points. If the resident consumes all four items in the amount served, the resident consumes 100% of breakfast. If the resident consumes two of the four food items served, then 50% of the breakfast would have been consumed. If three-fourths of a food item is consumed, give one point; for one-half consumed, give .5 points; for one- fourth or less, give no points. Total the points consumed x 100 and divide by the number of points given for that meal to give the percentage of meal consumed. Use these measurements when determining the amount of liquids consumed: Liquid measurements: 8 oz. cup = 240 cc, 6 oz. cup = 180 cc, 4 oz. cup = 120 cc, 1 oz. cup = 30 cc.

- Compare your findings with the facility's documentation to determine if the facility has accurately recorded the intake. Ask the staff if these findings are consistent with the resident's usual intake; and

- Note whether plates are being returned to the kitchen with 75% or more of food not eaten.

8. If concerns are noted with meal service, preparation, quality of meals, etc., interview the person(s) responsible for dietary services to determine how the staff are assigned and monitored to assure meals are prepared according to the menu, that the meals are delivered to residents in a timely fashion, and at proper temperature, both in the dining rooms/areas and in resident rooms.

NOTE: If concerns are identified in providing monitoring by supervisory staff during dining or concerns with assistance for residents to eat, evaluate nursing staffing in accord with 42 CFR 483.30(a), F353, and quality of care at 42 CFR 483.25(a)(2) & (3).

Task 6: Determination of Compliance:

o Compliance with 42 CFR 483.35(d)(1)(2), F364, Food

- The facility is compliant with this requirement when each resident receives food prepared by methods that conserve nutritive value, palatable, attractive and at the proper temperatures. If not, cite F364.

o Compliance with 42 CFR 483.35(b), F362, Dietary services, sufficient staff

- The facility is compliant with this requirement if they have sufficient staff to prepare and serve palatable and attractive, nutritionally adequate meals at proper temperatures. If not, cite F362.

NOTE: If serving food is a function of the nursing service, rather than dietary, refer to 42 CFR 483.30(a) F353.

o Compliance with 42 CFR 483.15(h)(1), F252, Environment

- The facility is compliant with this requirement if they provide a homelike environment during the dining services that enhances the resident's quality of life. If not, cite F252.

o Compliance with 42 CFR 483.70(g)(1)(2)(3)(4), F464, Dining and Resident Activities

- The facility is compliant with this requirement if they provide adequate lighting, ventilation, furnishings and space during the dining services. If not, cite F464.

INVESTIGATIVE PROTOCOL

NURSING SERVICES, SUFFICIENT STAFFING

Objectives:

o To determine if the facility has sufficient nursing staff available to meet the residents' needs.

o To determine if the facility has licensed registered nurses and licensed nursing staff available to provide and monitor the delivery of resident care.

Task 5C: Use:

NOTE: This protocol is not required during the standard survey, unless it is triggered in the event of care concerns/problems which may be associated with sufficiency of nursing staff. It is required to be completed for an extended survey.

This protocol is to be used when:

o Quality of care problems have been identified, such as: Residents not receiving the care and services to prevent pressure sore/ulcer(s), unintended weight loss and dehydration, and to prevent declines in their condition as described in their comprehensive plans of care, such as bathing, dressing, grooming, transferring, ambulation, toileting, and eating; and

o Complaints have been received from residents, families or other resident representatives concerning services, such as: Care not being provided, call lights not being answered in a timely fashion, and residents not being assisted to eat.

Procedures:

o Determine if the registered/licensed nursing staff are available to:

- Supervise and monitor the delivery of care by nursing assistants according to residents' care plans;

- Assess resident condition changes;

- Monitor dining activities to identify concerns or changes in residents' needs;

- Respond to nursing assistants' requests for assistance;

- Correct inappropriate or unsafe nursing assistants techniques; and

- Identify training needs for the nursing assistants.

o If problems were identified with care plans/services not provided as needed by the resident, focus your discussion with supervisory staff on the situations which led to using the protocol: how do they assure that there are adequate staff to meet the needs of the residents; how do they assure that staff are knowledgeable about the needs of the residents and are capable of delivering the care as planned; how do they assure that staff are appropriately deployed to meet the needs of the residents; how do they provide orientation for new or temporary staff regarding the resident needs and the interventions to meet those needs; and how do they assure that staff are advised of changes in the care plan?

o Determine if nursing assistants and other nursing staff are knowledgeable regarding the residents' care needs, such as: the provision of fluids and foods for residents who are unable to provide these services for themselves; the provision of turning, positioning and skin care for those residents identified at risk for pressure sore/ulcers; and the provision of incontinence care as needed;

o If necessary, review nursing assistant assignments in relation to the care and or services the resident requires to meet his/her needs;

o In interviews with residents, families and/or other resident representatives, inquire about the staff's response to requests for assistance, and the timeliness of call lights being answered; and

o Determine if the problems are facility-wide, cover all shifts or if they are limited to certain units or shifts, or days of the week. This can be based on information already gathered by the team with additional interviews of residents, families and staff, as necessary.

Task 6: Determination of Compliance:

NOTE: Meeting the State mandated staffing ratio, if any, does not preclude a deficiency of insufficient staff if the facility is not providing needed care and services to residents.

o Compliance with 42 CFR 483.30(a), F353, Sufficient Staff:

- The facility is compliant with this requirement if the faciltiy has provided a sufficient number of licensed nurses and other nursing personel to meet the needs of the residents on a twenty-four hour basis. If not, cite F353.

J. Closed Record Reviews.--Closed records are included in the total resident sample. If possible, select closed records of residents who have been identified through the use of offsite information concerning a particular care issue. If there is a care area that is an identified concern, try to obtain the closed records of residents who had the same care needs before death, discharge, or transfer. Document information on the HCFA-805, Sections C and D, as appropriate.

Look for information to determine compliance with quality of care and other requirements such as:

- o Assessment and care of infections;
- o Pressure sores;
- o Significant weight loss;
- o Restraints;
- o Multiple falls or injuries;
- o Discharge planning; and
- o Transfer and discharge requirements.

Unless there is a reason to review the entire record, focus the review on the appropriateness of care and treatment surrounding the resident's discharge or transfer, and the events leading up to that discharge or transfer. For example, if the survey team has identified a concern with inadequate identification and care of residents with infections, and several residents have recently been hospitalized with serious infections, the review would be a focused review on the care and assessment these residents received before they were hospitalized. In addition:

- o Look for documentation related to transfer, discharge, and bed-hold, including facility's discharge planning, notices, and reasons for facility-initiated moves (e.g., proper planning and transferring subsequent to a change in payor or care needs); and

- o Determine if within 30 days of the death of a resident, the facility conveyed the deceased resident's personal funds and a final accounting to the individual or probate jurisdiction administering the individual's estate as provided by State law (see 483.10(c)(6), F160).

K. Review of a Resident Receiving Hospice Care.--When a facility resident has also elected the Medicare hospice benefit, the hospice and the nursing facility must communicate, establish, and agree upon a coordinated plan of care for both providers which reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the facility. The plan of care must include directives for managing pain and other uncomfortable symptoms and be revised and updated as necessary to reflect the individual's current status.

The hospice must designate a registered nurse from the hospice to coordinate the implementation of the plan of care.

This coordinated plan of care must identify the care and services which the SNF/NF and hospice will provide in order to be responsive to the unique needs of the patient/resident and his/her expressed desire for hospice care.

The SNF/NF and the hospice are responsible for performing each of their respective functions that have been agreed upon and included in the plan of care. The hospice retains overall professional management responsibility for directing the implementation of the plan of care related to the terminal illness.

For residents receiving Hospice benefit care, evaluate if:

- The plan of care reflects the participation of the hospice, the facility, and the patient to the extent possible;
- The plan of care includes directives for managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect the individual's current status;
- Drugs and medical supplies are provided as needed for the palliation and management of the terminal illness and related conditions;
- The hospice and the facility communicate with each other when any changes are indicated to the plan of care;
- The hospice and the facility are aware of the other's responsibilities in implementing the plan of care;
- The facility's services are consistent with the plan of care developed in coordination with the hospice, (the hospice patient residing in a SNF/NF should not experience any lack of SNF/NF services or personal care because of his/her status as a hospice patient); and
- The SNF/NF offers the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The patient/resident has the right to refuse any services.

NOTE: If you have concerns about the resident in relation to care provided by the hospice agency then refer the issue to the State Agency (SA) responsible for surveying hospices.

L. Review of a Resident Receiving Dialysis Services.--When dialysis is provided in the facility by an outside entity, or the resident leaves the facility to obtain dialysis, the nursing home must have an agreement or arrangement with the entity in accord with 42 CFR 483.75 (h). This agreement/arrangement should include all aspects of how the resident's care is to be managed, including:

- Medical and non-medical emergencies;
- Development and implementation of the resident's care plan;
- Interchange of information useful/necessary for the care of the resident; and
- Responsibility for waste handling, sterilization, and disinfection of equipment.

If there is a sampled resident who is receiving dialysis care, evaluate the following, in addition to the standard Resident Review protocol:

- Whether medication is given at times for maximum effect;

o Whether staff know how to manage emergencies and complications, including equipment failure and alarm systems (if any), bleeding/hemorrhaging, and infection/bacteremia/septic shock;

o Whether facility staff are aware of the care of shunts/fistulas, infection control, waste handling, nature and management of end stage renal disease (including nutritional needs, emotional and social well being, and aspects to monitor); and

o Whether the treatment for this (these) resident(s), affects the quality of life, rights or quality of care for other residents (e.g., restricting access to their own space, risk of infections).

TASK 5D - QUALITY OF LIFE ASSESSMENT

A. Introduction.--The assessment of the quality of life and rights of residents incorporates review of selected tags within the following requirements:

o 42 CFR 483.10, Resident Rights;

o 42 CFR 483.12, Admission, Transfer and Discharge Rights;

o 42 CFR 483.13, Resident Behavior and Facility Practices;

o 42 CFR 483.15, Quality of Life; and

o 42 CFR 483.70, Physical Environment.

Since quality of life and quality of care are closely interrelated concepts, the survey process holistically integrates the quality of life assessment into the following tasks or sub-tasks:

o Task 5A, General Observations of the Facility (see Task 5A for further description);

o Task 5C, Resident Review, Sections A and B (see Task 5C for further description); and

o Task 5D, Quality of Life Assessment.

B. General Objectives.--The general objectives of the quality of life assessment are:

o To determine if the facility protects and promotes the rights of residents;

o To assess the impact of the facility's environment, facility schedules and policies, and staff interactions with residents on the quality of residents' lives;

o To determine if the facility is assisting residents to achieve and maintain their highest practicable well-being; and

o To determine if the facility provides equal access to quality care for all residents, regardless of payment source.

C. Quality of Life Protocols.-- Task 5D includes the following subtasks: interviews of interviewable residents, a meeting with the resident group or council, family interviews of residents who are not interviewable, and observations of these same non-interviewable residents. These are each described below.

1. Resident Interview.--These interviews are conducted with a subsample of interviewable residents from the resident sample. Refer to Table 1 in Task 4 to determine how many residents to interview. For example, in a facility with a census of 100, Table 1 directs the team to select 5 residents to interview.

It is helpful to divide the interview into two or more short segments. Seeing the resident more than once helps to establish rapport and also gives the resident a chance to think over the questions and provide more information later. Surveyors are encouraged to have several short conversations with interviewable residents during the course of the survey.

Locate a private place for the interview, and arrange interview times at the resident's convenience. Resident interviews should be conducted privately unless the resident expresses a preference to have a family member, staff member or the ombudsman present.

Prior to the interview, complete question 11 by writing any concerns you have discovered about this resident or about the facility that you would like to discuss with the resident. (You need not list issues that are already covered in the other questions of the interview.)

For example, during Offsite Survey Preparation, the team has noted that the facility has had repeated deficiencies for pest control of roaches. On the Initial Tour, you may have noticed the resident and her roommate were speaking angrily to each other. During the survey, the team has discovered disagreeable smells in this resident's unit, low levels of lighting in the dining room and some residents who go into others' rooms and rummage through drawers. Also add items you have discovered in the Resident Review about any of this resident's special needs and preferences that the facility should be taking into account. For example, a preference for a shower instead of a bath, or a need to have extra strong lighting because of a vision deficit. Add all these items to Question 11.

At the beginning of the first interview segment, use the probes on the first page of the interview to guide your explanation to the resident of the purpose of the interview. Discuss with the resident that you may want to write some of her/his answers down, and ask if that is all right. Then take a few minutes to establish rapport by letting the resident direct the conversation. For residents who are uncommunicative at first, use cues from their surroundings or from what you know about this resident to begin the conversation. Try to seek some commonality between the resident and yourself that will allow the resident to develop some ease in talking with you. For example, you might remark on family pictures and other personal items you see in the resident's room, or you might bring up a past occupation or hobby or a current activity preference of the resident that also interests you. Share a little about yourself, as appropriate.

Use the resident interview protocol to guide your conversation with the resident, but bring up topics in an order that is sensible to the conversation. Probe for further information if the answer the resident is giving is incomplete or unclear. After the interview, follow-up on the concerns the resident has raised. Include in your documentation both the facility practice in question and its effect on the resident. Share these concerns with team members so that they can pursue them during the remainder of the survey. (See the tag numbers in parentheses after particular questions for interpretive guidance on following up on resident comments.)

NOTE: There are some problems that a resident will express that are not within the scope of the long term care requirements. For example, a resident is complaining during an interview that he/she is displeased that he/she does not have a private room. This facility does not have private rooms, nor do the requirements mandate private rooms. If there is no issue related to one of the requirements, you need not investigate further.

2. Group Interview.--This interview is conducted with members of the resident council if one exists, or with an informal group of residents if there is no council. Staff members and residents' family members are not to be present at this interview unless the group specifically requests a certain
person's presence. The group need not be restricted to officers of the resident council. The survey team members should feel free to invite other residents they encounter who are able to converse and provide information. The resident council should also be encouraged to invite other residents at their discretion. It is preferable to keep the group size manageable (usually no more than 12), to facilitate communication. Residents who are not able to participate should not be included in this interview.

Prior to the meeting, review council minutes if they were provided by the council. Determine if there are any particular concerns you would like to discuss. Write in Question 13 these concerns and any other special concerns the team has learned about this facility during Offsite Survey Preparation, the Initial Tour, or during other observations and interviews. (You need not write concerns that are already covered in other questions of the interview.)

During the meeting, it may be helpful to have one surveyor conduct the interview while another takes notes. At the beginning of the meeting, use the probes on the first page of the protocol to guide you in introducing yourself and describing the purpose of the interview. Spend a few minutes establishing rapport with the group by letting them direct the conversation. If residents have nothing to say at this time, you may want to use a general question such as, "Tell me what life is like in this facility or, what makes a good day for you here?" Then continue with the protocol questions, probing for more information where necessary and presenting questions in an order that is sensible to the conversation. Get residents to talk in terms of actual situations or examples, using open-ended probes such as: "Can you tell me more about that? Can you give me an example?" or "How does that work here?"

After the meeting, follow-up on any concerns the residents have raised that are within the scope of the long term care requirements. Share these concerns with the team to focus their investigations.

3. Interview With Family Member or Friend of Non-Interviewable Resident.--The family interview is the first part of a two part protocol. The purpose of this interview is to obtain information about the prior and current preferences of a subsample of non-interviewable residents to help you assess whether the facility is individualizing daily life activities, care and services to the highest practicable level. The information gained through the interview will be used to complete Part D. below, the Observation of Non-Interviewable Resident. You will also follow-up on any concerns raised by the family member about the resident's treatment by the facility.

Use Table 1 in Task 4, to determine how many residents will receive the family interview and resident observation. For example, in a facility with a census of 100, 2 residents are selected.

Prior to the interview, review the relevant sections of the Minimum Data Set about past activities and preferences, and the resident's social history and activities assessment, if any. Begin completing this worksheet with information from the chart, and then use the interview to fill in missing information.
Information about a resident's past lifestyle and preferences may be more or less relevant, depending on the resident's condition and on the length of time spent in the nursing home. However, even after years of institutionalization, some features of a resident's prior life may

still be relevant, even if the resident is now debilitated and uncommunicative. You will also collect information about how the resident's current cognitive status and physical condition have changed his/her past preferences.

Family members do not always know the prior history of a nursing home resident. Therefore, Question 1 of this interview serves to obtain information about the family member's knowledge of the resident. If the family member's answers to Question 1 show that he/she has little or no knowledge of the resident's past history, you may want to discontinue this interview. If you choose to do so, end the interview with a general question such as, "What would you like to tell me about this facility and how your relative is treated?" This resident can still remain as part of the survey sample. Select another non-interviewable resident from the sample for a family interview and observation of non-interviewable resident protocol.

If the family member has partial knowledge, you may want to partially complete the interview with whatever information you can obtain in answer to the protocol questions.

Be aware that family members may have strong emotions about their relative's decline and institutionalization. Allow them to express their feelings, but gently direct them back to the questions of the protocol.

The interview may be conducted in person with a family member you have met on tour or by telephone, if necessary.

The second part of this protocol is the Observation of Non-Interviewable Resident. The purpose of this protocol is to obtain information through direct observation about the quality of life of the non-interviewable residents who have received family interviews.

Combine the information gained during the interview with what you have learned about the resident during the Resident Review to write any special items you wish to observe in item 1. What special needs and preferences does this resident have that the nursing home should be taking into account? For example, a resident is ambulatory with Alzheimer's Disease. Her prior life included meeting the school bus at 3 p.m. every day to pick up her children. Now she attempts to leave the facility around that time. What is the facility doing to accommodate this agenda of the resident? Another resident enjoyed being outdoors, and the family member stated she believes this resident would still like the opportunity to go outdoors. Is the facility responding to this preference? Another resident preferred tea to coffee. Is this preference taken into account? A resident preferred to be addressed as Mrs. Hernandez. How is this resident being addressed by staff? A resident liked to ski, but can no longer do so due to her condition. However, she may like to see a movie on skiing, have a skiing picture in her room, or go outside in the snow. Has the facility noted this preference? A resident always watched a certain soap opera every day. The family member says that even though she is now confused, this show may still attract her interest. Is this show being made available to the resident?

Use this protocol to complete approximately one hour of observations per resident, divided into short segments in at least three settings, at different times of the day. This need not be dedicated time--surveyors can complete other tasks while conducting this observation. Part of the time should be spent in a location in which you can observe what is happening as staff interact with the resident in his/her room. The remainder of the time should be divided among other locations frequented by the resident, including the dining room, activities rooms, other common areas, and therapy rooms. You may already have completed some observations of this resident prior to the interview, as part of the Resident Review. Continue making observations until you have covered all probes on the worksheet, including the special items you noted for observation. When making observations of the resident in particular settings, such as an activity or physical therapy, you need not observe for the entire duration of the activity or therapy session.

Use the probes in this protocol to guide your observations. Note the areas of concern on the Resident Review Worksheet. For each concern, be specific in noting time, location, and exact observations. Record what you see and hear, rather than a judgment of the situation. Instead of writing that the resident's dignity was violated by some interaction, simply record the interaction.

NOTE: During the individual, group and family interviews, ask questions regarding their awareness of to whom and how to report allegations, incidents and/or complaints. Share this information with the surveyor assigned to complete Task 5G.

Follow-up on areas of concern you observed. For example, you observed at lunch, that the resident was given only one food item at a time. The resident was reaching out for other food and his/her drink. Determine through staff interview and chart review if this method of feeding this resident has a therapeutic purpose or if it is an unnecessary restriction on his/her freedom to select the food he/she wishes to eat.

Share your observations with the team to assist them in their investigations of quality of life of other residents.

D. Follow-Up on Concerns Raised Through Interviews.--Whenever you have obtained information about areas of concern through resident interviews, attempt to investigate these areas through whatever means are appropriate. These might include interviews with other residents, staff, and families, and reviews of written facility information such as policies and procedures, and the admission rights information given to residents.

Sometimes these other sources will provide no other corroborating information. If that is the case, the team will determine during decision-making if the requirement is met or not met through the information obtained in resident interviews.

E. Confidentiality.--If residents or family members have stated during interviews that they do not want certain information they have told you in confidence to be shared with the facility, respect their wishes.

However, you can still investigate the issue. During the survey, you can discuss the issue with the team and make the topic the subject of other interviews and observations. For example, a resident has told you that certain staff "make fun" of him/her, but he/she asks you to keep that in confidence. You may not refer to the resident's comment in the statement of deficiencies. However, discuss this with the team and decide how best to pursue the matter while respecting the resident's wishes. Team members may want to address this topic with other residents, family members or the resident group. If you are aware of which staff are involved, attempt to observe these staff interacting with residents.

If other residents have complained about the same problem, you may refer to their comments generally as a group. For example, "Three out of five residents interviewed reported that . . ." Use your judgment to determine if your statement would compromise the resident's confidentiality.

TASK 5E - MEDICATION PASS

A. General Objective.--The general objective of the medication pass is to observe the actual preparation and administration of medications in order to assess compliance with 42 CFR 483.25(m).

B. General Procedures.--Record observations on the Medication Pass Worksheet (HCFA-677, Exhibit 88). The column marked "Record" is for the purpose of recording the

physician's actual order. Do this only if the physician's order differs from your observation of the administration of the drug. When observing the medication pass, do the following:

o See Guidance to Surveyors for specific information on conducting the medication pass.

o Be as neutral and unobtrusive as possible during the medication pass observation.

o Initially observe a minimum of 20-25 opportunities for errors (opportunities are both the drugs being administered and the doses ordered but not administered). Strive to observe as many individuals administering medications as possible. This provides a better overall picture of the accuracy of the facility's entire drug distribution system. Ideally, the medication observation could include residents representative of the care needs in the sample, or the actual sampled residents. This would provide additional information on these residents, and provide a more complete picture of the care they actually receive. For example, if blood sugars are a problem, insulin administration may be observed. If eye infections are a problem, antibiotic eye drops may be observed, if residents are in pain, as needed pain medications may be observed, etc. Observe different routes of administration (i.e., eye drops, injections, NG administration, inhalation). If you found no errors after reconciliation of the pass with the medical records, this task is complete. If you found 1 or more errors, observe another 20-25, opportunities for errors.

o Calculate the facility's medication error rate. If you determine that the facility's significant and non-significant error rate is 5 percent or more, or that one significant error has occurred, a medication error deficiency exists.

TASK 5F - QUALITY ASSESSMENT AND ASSURANCE REVIEW

A. General Objectives.--The quality assessment and assurance review protocol is designed to determine if:

1. A Quality Assessment and Assurance Committee exists and meets in accordance with the regulatory requirements of 42 CFR 483.75(o); and

2. The committee has a method, on a routine basis, to identify, respond to, and evaluate its response to issues which require quality assessment and assurance activity.

Facility compliance with CFR 483.75(o) is not dependent upon identification of quality deficiencies identified by the survey team, but rather by survey team identification of an effective QA committee that is constituted and meets according to the regulatory requirements, and identifies and resolves quality deficiencies pertinent to the quality of care and quality of life of facility residents.

B. General Procedures.--

1. The review of requirements at 42 CFR 483.75(o) will be conducted only after the Phase 2 sampling meeting.

2. The review is postponed until this time to ensure that facility quality deficiencies are not identified by the survey team through the use of records of the facility's quality assessment and assurance activities.

3. The protocol has 2 parts:

a. Part 1 applies to all facilities; and

b. Part 2 is initiated and builds upon Part 1, when the survey team has identified actual or probable quality deficiencies during the first phase of the survey.

C. Protocol.--

1. Part 1 - All Facilities.--Through interview with administrative staff and Quality Assessment and Assurance Committee members, determine if:

o The facility has a Quality Assessment and Assurance Committee;

o The committee consists of, at a minimum, the Director of Nursing, a physician designated by the facility and 3 members of the facility staff;

o The committee meets at least quarterly;

o The committee has a formal method to identify issues in the facility which require quality assessment and assurance activities; and

o The committee has a formal method to respond to identified quality deficiencies and evaluate the effectiveness of that response.

Part 1 should not include a review of committee minutes that address actual quality deficiencies. A written description of the Committee's process or protocol for identifying quality deficiencies, coupled with interviews indicating that this process is actually followed, is satisfactory documentation for Part 1.

2. Part 2 - Facilities With Identified Actual or Probable Quality Deficiencies.--The survey team conducts this investigation through interviews with Committee members and, as necessary, directs care staff to determine if the facility:

o Has identified quality deficiencies;

o Has developed and implemented a plan to address those quality deficiencies; and

o Has evaluated, or has a plan to evaluate, the effectiveness of the planned implementation.

The surveyors' goal in this part of the survey is to determine whether the facility has an effective method of identifying quality deficiencies and dealing with them. You may do this by asking the facility to describe a sample of the quality deficiencies they have identified and dealt with. Surveyors should be guided by the following principles in this part of the survey:

o The surveyors' goal during this part of the survey is to ascertain whether the facility has a QA committee which addresses quality concerns and that staff know how to access that process;

o Surveyors may ask QA committee members and/or direct care staff how the QA committee functions, what the quality assurance and assessment process in the facility is, whether direct care staff know how to access the QA process and committee, and whether the QA committee is responsive to QA concerns submitted to it;

o Committee records and/or minutes, including those identifying details of the

specific quality deficiencies which have been dealt with or are currently being dealt with should not be reviewed;

o Surveyors may also ask the facility (i.e., the QA committee) to describe a sample of the types of quality deficiencies the facility has identified and how it addressed them. These need not be practices that the survey team has identified as concerns. Such a sample should consist only of quality deficiencies which the facility believes it has resolved through its quality assurance process (i.e., past corrected problems);

o Determine compliance in this phase by interviewing direct care staff to determine if they are familiar with the specific plan(s) for care described by the QA committee and have implemented them. It is not necessary that direct care staff know that the care they are providing is the result of a quality assurance plan, however, they should be implementing the plan as develop as a routine part of their resident care. Also, if the plan described by the QA committee is not being followed, determine whether there is a justifiable reason for the (for example, the facility replaced the process described by the QA committee with a different process based on updated protocols, medical knowledge, etc.);

o If the facility has been out of compliance with a regulatory requirement between two surveys in which they were in compliance, that past noncompliance will not be cited by the survey team if a quality assurance program is in place and has corrected the noncompliance. An exception to this policy may be made in cases of egregious past noncompliance.

TASK 5G - ABUSE PROHIBITION REVIEW

A. General Objective.--To determine if the facility has developed and operationalized policies and procedures that prohibit abuse, neglect, involuntary seclusion and misappropriation of property for all residents. The review includes components of the facility's policies and procedures as contained in the Guidance to Surveyors at 42 CFR 483.13(c), F226. (See Guidance to Surveyors for further information.)

These include policies and procedures for the following:

o Screening of potential hirees;

o Training of employees (both for new employees, and ongoing training for all employees);

o Prevention policies and procedures;

o Identification of possible incidents or allegations which need investigation;

o Investigation of incidents and allegations;

o Protection of residents during investigations; and

o Reporting of incidents, investigations, and facility response to the results of their investigations.

B. General Procedures:

o Utilize the Abuse Prohibition Investigative Protocol to complete this task.

INVESTIGATIVE PROTOCOL

ABUSE PROHIBITION

Objective:

To determine if the facility has developed and operationalized policies and procedures that prohibit abuse, neglect, involuntary seclusion and misappropriation of property for all residents.

Use:

Use this protocol on every standard survey.

Task 5G Procedures:

o Obtain and review the facility's abuse prohibition policies and procedures to determine that they include the key components, i.e. screening, training, prevention, identification, investigation, protection and reporting/response. (See Guidance to Surveyors at F226.) It is not necessary for these items to be collected in one document or manual.

o Interview the individual(s) identified by the facility as responsible for coordinating the policies and procedures to evaluate how each component of the policies and procedures is operationalized, if not obvious from the policies. How do you monitor the staff providing and/or supervising the delivery of resident care and services to assure that care service is provided as needed to assure that neglect of care does not occur? How do you determine which injuries of unknown origin should be investigated as alleged occurrences of abuse? How are you ensuring that residents, families, and staff feel free to communicate concerns without fear of reprisal?

o Request written evidence of how the facility has handled alleged violations. Select 2-3 alleged violations (if the facility has this many) since the previous standard survey or the previous time this review has been done by the State.

- Determine if the facility implemented adequate procedures:
  + For reporting and investigating;
  + For protection of the resident during the investigation;
  + For the provision of corrective action;

NOTE: The reporting requirements at 483.13(c) specify both a report of the alleged violation and a report of the results of the investigation to the State survey agency.

- Determine if the facility reevaluated and revised applicable procedures as necessary.

o Interview several residents and families regarding their awareness of to whom and how to report allegations, incidents and/or complaints. This information can be obtained through the resident, group, and family interviews at Task 5D.

o Interview at least five (5) direct care staff, representing all three shifts, including activity staff and nursing assistants, to determine the following:

- If staff are trained in and are knowledgeable about how to appropriately intervene in situations involving residents who have aggressive or catastrophic reactions.

NOTE: Catastrophic reactions are extraordinary reactions of residents to ordinary stimuli, such as the attempt to provide care. One definition in current literature is as follows: ". . . catastrophic reactions [are] defined as reactions or mood changes of the resident in response to what may seem to be minimal stimuli (eg.: bathing, dressing, having to go to the bathroom, a question asked of the person) that can be characterized by weeping, blushing, anger, agitation, or stubbornness. Catastrophic reactions and other behaviors of Alzheimer residents: Special unit compared to traditional units. Elizabeth A Swanson, Meridean L. Maas, and Cathleen Buckwalter . Archives of Psychiatric Nursing. Vol. VII No. 5 (October, 1993). Pp. 292-299.

- If staff are knowledgeable regarding what, when and to whom to report according to the facility policies.

o Interview at least three front line supervisors of staff who interact with residents (Nursing, Dietary, Housekeeping, Activities, Social Services). Determine how they monitor the provision of care/services, the staff/resident interactions, deployment of staff to meet the residents' needs, and the potential for staff burnout which could lead to resident abuse.

o Obtain a list of all employees hired within the previous four months, and select 5 from this list. Ask the facility to provide written evidence that the facility conducted pre-screening based on the regulatory requirements at 42 CFR 483.13(c).

Task 6 Determination of Compliance:

Take account of all the information gained during this review as well as all other information gained during the survey. When a deficiency exists, determine if F225 or F226 provides the best regulatory support for the deficiency.

o 483.13(c), F226, Staff Treatment of Residents:

- The facility is compliant with this requirement if they have developed and implemented written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. If not, cite at F226.

o 483.13(c)(1)(2)(3)and (4), F225, Staff Treatment of Residents:

- The facility is compliant with this requirement if they took appropriate actions in the areas of screening, reporting, protecting, investigating and taking appropriate corrective actions. If not, cite at F225.

TASK 6 - INFORMATION ANALYSIS FOR DEFICIENCY DETERMINATION

A. General Objectives.--The objectives of information analysis for deficiency determination are:

- To review and analyze all information collected and to determine whether or not the facility has failed to meet one or more of the regulatory requirements; and
- To determine whether to conduct an extended survey.

B. Overview.--The worksheets and procedures are designed to assist the surveyor in gathering, investigating, organizing, and analyzing information about the quality of services provided by the facility in order to determine whether the facility has failed to meet long term care requirements.

The information gathering portions of the survey have focused on the resident and the delivery of services by the facility using observation, interview and record review as sources of information. The information analysis and decision-making portion of the survey focuses on making determinations about whether the facility meets requirements.

Information analysis and decision Making builds on discussions of the daily team meetings, which should include discussions of observed problems, areas of concern, and possible failure to meet requirements.

Decisions about deficiencies are to be team decisions with each member of the team, including specialty surveyors (see Section I.C.), having input into the decisions. The team coordinator or designee should document the deficiency decisions and the substance of the evidence on the HCFA-807.

For initial surveys, a determination must be made regarding whether the facility meets every long term care requirement.

C. Decision-Making Process.--Each member of the team should review his or her worksheets to identify concerns and specific evidence relating to requirements that the facility has potentially failed to meet. In order to identify the facility's deficient practices and to enable collating and evaluating the evidence, worksheets should reflect the source of the evidence and should summarize the concerns on relevant data tags.

- Begin the decision-making task by taking into account the daily discussions, the findings documented on the worksheets, discussions with the facility, observations over the course of the survey, and the discussions regarding definitions of deficiencies in the following section. At a minimum, focus on the regulatory groupings 42 CFR 483.10 Resident Rights, 42 CFR 483.13 Resident Behavior and Facility Practice, 42 CFR 483.15 Quality of Life, 42 CFR 483.20, Resident Assessment and 42 CFR 483.25 Quality of Care. Gather pertinent information from all worksheets for the pertinent to the particular requirements being reviewed (e.g., documentation from all worksheets concerning resident rights). In general, what is the facility's performance in meeting these requirements? Does the facility protect and promote resident rights? Discuss results of the information gathering phase in the context of facility conformance with these resident-centered requirements and the examples of resident-facility interactions that cause you to believe there may be deficiencies.
- Prioritize your review of worksheets so that the first information the team discusses relates to those requirements that the facility has potentially failed to meet. For

example, what documentation on the Quality of Life Assessment worksheet supports the belief that the facility does not protect and promote resident rights? What information on other worksheets supports or does not support the team's assessment of Resident Rights? Evaluate the specifics of the regulatory language and the specific data you have collected (e.g., observation, resident, family and staff interview information) with respect to the facility's performance in each requirement. Review the worksheets on an individual tag-by-tag basis. If your data indicate that the facility has not met a specific requirement (see Task 6, Section D), document that deficiency.

o In order to ensure that no requirements are missed, proceed through the requirements sequentially as they appear in the interpretive guidelines, preferably section by section. Findings/evidence within each section should be shared by each team member during this discussion. Consider all aspects of the requirements within the tag/section being discussed and evaluate how the information gathered relates to the specifics of the regulatory language and to the facility's performance in each requirement. The team should come to consensus on each requirement for which problems have been raised by any member. If no problems are identified for a particular tag number during your information gathering process, then no deficiency exists for that tag number

o The team coordinator, or a designee, collates all information and records the substance of the decisionmaking discussion on the HCFA-807. (See Exhibit 98.)

o Determine if there is substandard quality of care.

o If substandard quality of care exists conduct an extended survey.

D. Deficiency Criteria.--To determine if a deficiency exists, use the following definitions and guidance:

o A "deficiency" is defined as a facility's failure to meet a participation requirement specified in the Social Security Act or in Part 483, Subpart B (i.e., 42 CFR 483.5 - 42 CFR 483.75).

o To help determine if a deficiency exists, look at the language of the requirement. Some requirements need to be met for each resident. Any violation of these requirements, even for one resident is a deficiency.

o Other requirements focus on facility systems.

For some requirements, especially those in the regulatory grouping of Quality of Life (42 CFR 483.15), the team will evaluate the sum of the staff actions and/or decisions for an individual resident to determine if the requirement is met for that individual. Quality of Life requirements are best evaluated comprehensively, rather than in terms of a single incident. However, a single incident which is considered severe enough may result in a deficiency.

Certain facility systems requirements must be met in an absolute sense (e.g., a facility must have a RN on duty seven days a week, unless it has received a waiver). Other facility system requirements are best evaluated comprehensively, rather than in terms of a single incident. In evaluating these requirements the team will examine both the individual parts of the system (e.g., the adequacy of the infection control protocol, the adequacy of facility policy on hand washing), as well as the actual implementation of that system.

E. Evidence Evaluation.--The survey team must evaluate the evidence documented during the survey to determine if a deficiency exists due to a failure to meet a requirement and if there

are any negative resident outcomes due to the failure. Failure to meet requirements related to quality of care, resident rights, and quality of life generally falls into two categories:

1. Potential or Actual Physical, Mental or Psychosocial Injury or Deterioration to A Resident Including Violation of Residents' Rights.--Some situations which illustrate this level of harm could be:

- o Development of, or worsening of, a pressure sore;
- o Loss of dignity due to lying in a urine-saturated bed for a prolonged period; and
- o Social isolation caused by staff failure to assist the resident in participating in scheduled activities.

This category of negative outcome may be identified when an identified facility practice is so divergent from accepted principles of practice that harm has occurred or a future negative outcome or harm is probable.

An example would be nurse aides in a facility who often fail to wash their hands between caring for residents. In this example, there is a strong potential for harm although there has been no evidence of a high facility infection rate, or of infections spreading from one resident to another. Should a resident contract an infection or become colonized with a highly contagious bacteria, there is a high potential for a major outbreak of nosocomial infection.

2. Lack of (or the Potential for Lack of) Reaching the Highest Practicable Level of Physical, Mental or Psychosocial Well-Being.--No deterioration occurred, but the facility failed to provide necessary care for resident improvement. For example:

a. The facility identified the resident's desire to reach a higher level of ability, e.g., improvement in ambulation, and care was planned accordingly. However, the facility failed to implement, or failed to consistently implement the plan of care, and the resident failed to improve, i.e., did not reach his/her highest practicable well-being;

b. The facility identified a need in the comprehensive assessment, e.g., the resident was withdrawn/depressed, but the facility did not develop a care plan or prioritize this need of the resident, planning to address it at a later time. The resident received no care or treatment to address the need and did not improve (i.e., remained withdrawn/depressed). Therefore, the resident was not given the opportunity to reach his/her highest practicable well-being;

c. The facility failed to identify the resident's need/problem/ability to improve, e.g., the ability to eat independently if given assistive devices, and, therefore, did not plan care appropriately. As a result, the resident failed to reach his/her highest practicable well-being, i.e., eat independently.

d. A facility's written procedures or oral explanations do not provide information about which residents are supposed to be fully informed (e.g., the resident is provided treatment which they may have wished to refuse).

If the resident is the primary source of information, the team should conduct further information-gathering and analysis. This may include additional interviews with family and staff or record reviews to supplement or corroborate the resident's report. If additional sources of information are not available, determine if the interviewees are reliable sources of information

and if the information received is accurate. If so, citation of a deficiency may be based on resident information alone.

In cases where residents are unable to speak for themselves, the survey team should assess how most people would react to the situation in question. For example, a female resident who is unable to express herself is wheeled down the hall in a wheelchair on the way to her shower with only a towel partially covering her body. The team will decide if this incident is inappropriate because the resident is unable to express herself. Quality of life and Residents' Rights requirements are most often evaluated using this type of analysis.

F. Determination of Substandard Quality of Care.--The team must determine if substandard quality of care exists. Substandard quality of care is defined as one or more deficiencies related to participation requirements under 42 CFR 483.13, Resident Behavior and Facility Practices, 42 CFR 483.15, Quality of Life, or 42 CFR 483.25, Quality of Care which, constitute either immediate jeopardy to resident health or safety pattern or widespread deficiencies at severity level 3, or widespread deficiencies at severity level 2. (See Section V., Deficiency Categorization.)

G. Special Circumstances.--Substandard quality of care and immediate jeopardy determinations trigger additional survey tasks and must be determined during the information gathering tasks of the survey and/or during information analysis and decision-making.

Immediate jeopardy is defined as a situation in which the facility's failure to meet one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. At any time during the survey, if one or more team members identifies possible immediate jeopardy, the team should meet immediately to confer. The guiding principles to determine immediate jeopardy and serious threat make it clear that the threat can be related to mental, as well as physical well-being, and that the situation in question need not be a widespread problem. If the team concurs, the team coordinator must consult immediately with his/her supervisor. If the supervisor concurs that the situation constitutes immediate jeopardy, the team coordinator informs the facility administrator or designee that the immediate jeopardy termination procedures are being invoked. The team coordinator should explain the nature of the immediate jeopardy to the administrator or designee. The survey team should complete the entire survey. See Appendix Q for guidance regarding determination of immediate jeopardy, and §3010 for procedures to follow if the immediate jeopardy termination procedures are invoked.

When surveyors suspect substandard quality of care (SQC), they expand the standard (or abbreviated) survey sample as necessary to determine scope (Refer to Task 4, Supplementary Sample for further information). If there is no deficiency(ies) classified as substandard care and there is a deficiency under the regulatory Groupings of 42 CFR 483.13, 42 CFR 483.15 and/or 42 CFR 483.25, that are classified as an isolated incident of severity level 3, or, as a pattern of severity level 2, then you must determine if you have sufficient evidence to make the decision that there is not substandard quality of care.

If the evidence is not adequate and the number of observations only allowed for isolated scope when there is a severity level 3, or pattern for scope when there is a severity level 2, then expand the sample to include additional reviews of that requirement. For example, if residents in the facility are receiving care for a colostomy, and for the one resident with a colostomy in your sample, you determined that care provided caused actual harm to the resident, you would have a deficiency of isolated actual harm, but you would not have sufficient evidence to determine that there was substandard care. Thus, you would need to expand your sample before determining that substandard care did or did not exist. On the other hand, if the number of individuals with a colostomy in the facility was the same (6), and 4 residents with colostomies were included in your sample and only one had deficient care, there would be no need

to expand your sample. If the team verifies the existence of SQC, they inform the administrator that the facility is in SQC and an extended (or partial extended) survey will be conducted. If expanding the sample determines that SQC does not exist, no extended or partial extended survey will be conducted.

TASK 7 - EXIT CONFERENCE

A. General Objective.--The general objective of the exit conference is to inform the facility of the survey team's observations and preliminary findings.

B. Conduct of Exit Conference.--Conduct the exit conference with facility personnel. Invite the ombudsman and an officer of the organized residents group, if one exists, to the exit conference. Also, invite one or two residents to attend. The team may provide an abbreviated exit conference specifically for residents after completion of the normal facility exit conference. If two exit conferences are held, notify the ombudsman and invite the ombudsman to attend either or both conferences.

Do not discuss survey results in a manner that reveals the identity of an individual resident. Provide information in a manner that is understandable to those present (e.g., say the deficiency "relates to development of pressure sores," not "tag F314").

Describe to the facility the team's preliminary deficiency findings and let them know they will receive a report of the survey which will contain any deficiencies that have been cited against the facility (HCFA-2567). If requested, provide the facility with a list of residents included in your standard survey sample. Do not give the team's Roster/Sample Matrixes to the facility, as they contain confidential information.

If an extended survey is required and the survey team cannot complete all or part of the extended survey prior to the exit conference, inform the administrator that the deficiencies as discussed in the conference may be amended upon completion of the extended survey. (See §2724 for additional information concerning exit conferences.)

During the exit conference, provide the facility with the opportunity to discuss and supply additional information that they believe is pertinent to the identified findings. Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances where the facility is not aware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

III. THE EXTENDED SURVEY AND PARTIAL EXTENDED SURVEY

A. Extended and/or Partial Extended Survey.--Conduct an extended survey subsequent to a standard survey and conduct a partial extended survey subsequent to an abbreviated survey when you have determined that there is a substandard quality of care in:

- 42 CFR 483.13, Resident behavior and facility practices;
- 42 CFR 483.15, Quality of life; and/or
- 42 CFR 483.25, Quality of care.

When conducting the extended/partial extended survey, at a minimum, fully review and verify compliance with each tag number within 42 CFR 483.30, Nursing Services; 42 CFR 483.40, Physician Services; and 42 CFR 483.75, Administration. Focus on the facility's policies and

procedures that may have produced the substandard quality of care. For an extended survey and partial extended survey, as appropriate, include a review of staffing, inservice training and the infection control program. An extended/partial extended survey explores the extent to which structure and process factors such as written policies and procedures, staff qualifications and functional responsibilities, and specific agreements and contracts of the facility may have contributed to the outcomes. If the extended/partial extended survey was triggered by a deficiency in quality of care, conduct a detailed review of the accuracy of resident assessment. During the partial extended survey, consider expanding the scope of the review to include a more comprehensive evaluation of the requirements at 42 CFR 483.13, 42 CFR 483.15, and/or 42 CFR 483.25 in which substandard quality of care was found.

Document your observations from the extended or partial extended survey on the HCFA-805, (see Exhibit 93) or the HCFA-807 (see Exhibit 95).

B. Review of the Accuracy of Resident Assessments During an Extended/Partial Extended Survey.--The objective of this review is to determine if resident assessments are accurate.

If an extended/partial extended survey is conducted based on substandard quality of care in Quality of Care (42 CFR 483.25), review the accuracy of resident assessments by:

o Reviewing a sample of comprehensive resident assessments completed no more than 30 days prior to conducting the survey;

o Comparing your observations of the resident with the facility's assessment;

o Conducting the number of assessment reviews needed to make a decision concerning the accuracy of the facility's resident assessments; and

o Determining if your observations of the resident, and interviews with resident/staff/family, "match" the facility's assessment (or specific portions of the assessment) of the resident. If your observations and interviews do not "match," investigate further.

Record the indepth review of the accuracy of resident assessments on page 3 of the HCFA-805. (See Exhibit 93.)

C. Timing for Conducting the Extended Survey and Partial Extended Survey.-Conduct the extended or partial extended survey:

o Prior to the exit conference, in which case the facility will be provided with information from the standard, abbreviated standard, partial extended or extended surveys; or

o Not later than 2 weeks after the standard/abbreviated survey is completed, if the team is unable to conduct the extended survey or partial extended survey concurrent with the standard survey or the abbreviated survey. Advise the facility's administrator that there will be an extended or partial extended survey conducted and that an exit conference will be held at the completion of the survey.

IV. WRITING THE STATEMENT OF DEFICIENCIES

A. General Objective.--The general objective of this section is to write the statement of deficiencies in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Indicate the data prefix tag and regulatory citation, followed by a summary of the evidence and supporting observations

using resident identifiers. This documentation must be written in language specific enough to use to identify levels of severity and scope at the completion of the survey. If information was identified during confidential resident interviews, do not include a resident identifier when recording the source of the evidence. List the data tags in the order specified in the Code of Federal Regulations.

When a facility is in substantial compliance, but has deficiencies which are isolated with no actual harm and potential for only minimal harm, the deficiencies are recorded on the "Notice of Isolated Deficiencies" instead of on the HCFA-2567. A plan of correction is not required, but a facility is expected to correct all deficiencies.

The statement of deficiencies should:

- o Specifically reflect the content of each requirement that is not met;
- o Clearly identify the specific deficient entity practices and the objective evidence concerning these practices;
- o Identify the extent of the deficient practice, including systemic practices, where appropriate; and
- o Identify the source(s) of the evidence (e.g., interview, observation, or record review).

Following deficiency categorization (Section V), enter on Form HCFA-2567L the letter corresponding to the box of the scope and severity grid (SOM Part 7, §7400 E.) for at least any deficiency which constitutes substandard quality of care and any deficiency which drives the choice of a required remedy category. Enter these letters in ID prefix tag column immediately below the tag number of the Form HCFA-2567L.

V. DEFICIENCY CATEGORIZATION

A. General Objective.--After the survey team determines that a deficiency(ies) exists, assess the effect on resident outcome (severity level) and determine the number of residents potentially or actually affected (scope level). Use the results of this assessment to determine whether or not the facility is in substantial compliance or is noncompliant. When a facility is noncompliant, consider how the deficient practice is classified according to severity and scope levels in selecting an appropriate remedy. (See §7400 for discussion of remedies.)

Scope and severity determinations are also applicable to deficiencies at §483.70(a), Life Safety from Fire.

B. Guidance on Severity Levels.--There are four severity levels. Level 1, no actual harm with potential for minimal harm; Level 2, no actual harm with potential for more than minimal harm that is not immediate jeopardy; Level 3, actual harm that is not immediate jeopardy; Level 4, immediate jeopardy to resident health or safety. These four levels are defined accordingly:

1. Level 1 is a deficiency that has the potential for causing no more than a minor negative impact on the resident(s).

2. Level 2 is noncompliance that results in no more than minimal physical, mental

and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

3. Level 3 is noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.

4. Level 4 is immediate jeopardy, a situation in which immediate corrective action is necessary because the facility's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. (See Appendix Q.)

C. Guidance on Scope Levels.--Scope has three levels: isolated; pattern; and widespread. The scope levels are defined accordingly:

o Scope is isolated when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations.

o Scope is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility.

o Scope is widespread when the problems causing the deficiencies are pervasive in the facility and/or represent systemic failure that affected or has the potential to affect a large portion or all of the facility's residents. Widespread scope refers to the entire facility population, not a subset of residents or one unit of a facility. In addition, widespread scope may be identified if a systemic failure in the facility (e.g., failure to maintain food at safe temperatures) would be likely to affect a large number of residents and is, therefore, pervasive in the facility.

D. General Procedures.--After the team makes a decision to cite a deficiency(ies), evaluate the deficient practice's impact on the resident(s) and the prevalence of the deficient practice. Review deficiency statements, worksheets, and results of team discussions for evidence on which to base these determinations. The team may base evidence of the impact or prevalence for residents of the deficient practices on record reviews, interviews and/or observations. Whatever the source, the evidence must be credible.

After determining the severity level of a deficient practice, determine scope. When determining scope, evaluate the cause of the deficiency. If the facility lacks a system/policy (or has an inadequate system) to meet the requirements and this failure has the potential to affect a large number of residents in the facility, then the deficient practice is likely to be widespread. If an adequate system/policy is in place but is being inadequately implemented in certain instances, or if there is an inadequate system with the potential to impact only a subset of the facility's population, then the deficient practice is likely to be pattern. If the deficiency affects or has the potential to affect one or a very limited number of residents, then the scope is isolated.

If the evidence gathered during the survey for a particular requirement includes examples of various severity or scope levels, surveyors should generally classify the deficiency at the highest level of severity, even if most of the evidence corresponds to a lower severity level. For example, if there is a deficiency in which one resident suffered a severity 3 while there were widespread findings of the same deficiency at severity 2, then the deficiency would be generally classified as severity 3, isolated.

VI. POST SURVEY REVISIT (FOLLOW-UP)

In accordance with §7317, the State agency conducts a revisit to confirm that the facility is in compliance and has the ability to remain in compliance. The purpose of the post-survey revisit (follow-up) is to re-evaluate the specific care and services that were cited as noncompliant during the original standard, abbreviated standard, extended or partial extended survey(s). Ascertain the status of corrective actions being taken on all requirements not in substantial compliance. Section 7304 contains the 4 elements a facility must address in developing acceptable plan of correction. One of these elements is what continuous quality improvement system(s) a facility has in place to monitor its performance in identifying the deficient practice/care and assuring that it does not recur.

Because this survey process focuses on the care of the resident, revisits are almost always necessary to ascertain whether the deficient practices have indeed been corrected. The nature of the noncompliance dictates the scope of the revisit. For example, do not perform another drug pass if no drug distribution related deficiencies were cited on the initial survey. Do interviews and closed record reviews, as appropriate. Prior to the revisit, review appropriate documents, including the plan of correction to focus the revisit review.

Conduct as many survey tasks as needed to determine compliance status. However, the team is not prohibited from gathering information related to any requirement during a post-survey revisit.

When selecting the resident sample for the revisit survey, determine the sample size using 60% of the sample size for a standard survey as described in Table 1, Resident Sample Selection. (Phase 1 sample size is 60%.) The follow-up survey does not require a 2 Phase sample selection.

Focus on selecting residents who are most likely to have those conditions/needs/problems cited in the original survey. If possible, include some residents identified as receiving substandard quality of care during the prior survey. If, after completing the revisit activities, you determine that the cited incidence(s) of noncompliance was not corrected, initiate enforcement action, as appropriate. (See §7400 for specific guidance concerning initiation of enforcement action.)

Use appropriate HCFA forms during this survey. However, if the need for documentation is minimal, use the Surveyor Notes Worksheet (HCFA-808). (See Exhibit 95 to record the results of the revisit.)

VII. ABBREVIATED STANDARD SURVEYS

A. Complaint Investigations.--The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements if its review of the allegation concludes that:

- o A deficiency in one or more of the requirements may have occurred;
- o Only a survey can determine whether a deficiency or deficiencies exist; and

o The complaint is general or specific and may involve staff, residents, volunteers, the physical environment or administration.

Complaint investigations follow, as appropriate, the pertinent survey tasks, and information gathered is recorded on the appropriate survey worksheets. However, if the documentation required is minimal, use the HCFA-807 to record information during the complaint investigation. Record deficiencies on the HCFA-2567 or the Notice of Isolated Deficiencies, or both as applicable.

The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

The timing, scope, duration and conduct of a complaint investigation are at the discretion of the State survey agency, except when the complaint involves an allegation of immediate jeopardy to resident health and safety, which must be investigated within 2 working days of receipt. (See §7700.) The team should conduct the necessary investigation to resolve the complaint. If the complaint concerns conditions on a certain day (e.g., on weekends), or on a certain shift (e.g., 11 p.m. - 7 a.m.), the survey agency should make an attempt to investigate it at the time relevant to the complaint. In most cases, the following tasks, or portion of tasks, should be performed in a complaint investigation:

1. Task 1 - Offsite Survey Preparation.--Obtain as much information as you can about the complaint before you begin to plan your investigation, including:

a. Name of complainant;

b. Nature of the complaint - describe exactly the facts of the complaint situation;

c. Information about when the complaint situation occurred, whether it was an isolated event or an ongoing situation - date, time, time between different events;

d. Place where the incident happened - care unit, resident room;

e. How it happened - sequence of events;

f. Whether a resident or a family member of a resident was involved;

g. Witnesses to complaint situation - anyone who saw incident happen;

h. Staff or other residents involved; and

i. Other persons involved - volunteers or visitors.

Review any information about the facility that you think would be helpful to know in planning your investigation such as Oscar Reports 3 and 4, and State agency files. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to and substantiated by the ombudsman.

Review the related regulatory requirements or standards that pertain to the complaint. For example, if it is a complaint about abuse, review the requirements at 42 CFR 483.13.

Plan the investigation. Before you go to the facility, plan what information you need to obtain during the complaint investigation based on the information you have already acquired. Consider practical methods to obtain that information.

2. Task 2 - Entrance Conference/Onsite Preparatory Activities.--Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's administrator of the general purpose of the visit. It is important to let the facility know why you are there, but protect the confidentiality of those involved in the complaint. Do not release information that will cause you to lose opportunities for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, if the complaint is that food that is intended to be served hot is always served cold, you would not tell the facility the exact complaint. Rather, you may say it is a situation related to dietary requirements.

3. Task 5 - Information Gathering.--The order and manner in which you gather information will depend on the type of complaint you are investigating. Conduct comprehensive, focused, and/or closed record reviews as appropriate for the type of complaint. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Do your information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As you obtain information, use what you have learned to determine what needs to be clarified or verified as you continue the investigation.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e., what happened to the resident and the outcome, investigate what facility practice(s) or procedures effective the occurrence of the incident. EXAMPLE: It was verified through your investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (such as turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

Record review: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

EXAMPLE: For a complaint of verbal and physical abuse, review the record to determine the resident's mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident's demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he or she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff

involved. In order to maintain the confidentiality of your witnesses, change the order of interviews if necessary. You may not want to interview the person who made the complaint first, as that may identify the person to the facility as the complainant. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines you need for other identified witnesses and revise outlines as new information is obtained.

4. Task 6 - Information Analysis.--Review all information collected. If there are inconsistencies, do additional data collection as needed, to resolve the inconsistencies. Determine if there is any other information still needed.

Determine whether:

- o The complaint is substantiated;
- o The facility failed to meet any of the regulatory requirements; and
- o The facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.

5. Task 7 Exit Conference: Advise the administrator of the complaint investigation findings and any present deficiencies. Do not inform him/her of confidential information unless the individual who provided you with the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected (past noncompliance), notify the facility orally and in writing that the complaint was substantiated because deficiencies existed at the time that the complaint situation occurred. (See Task 5F, Section A and §7510 for specific information when a CMP is imposed for egregious non-compliance concerning past noncompliance.)

If the complaint is unsubstantiated, that is the surveyor(s) cannot determine that it occurred and there is no indication of deficient practice, notify the facility of this decision.

Follow your usual office procedure in notifying the resident and/or person who made the complaint of your findings.

B. Substantial Changes in a Facility's Organization and Management.--If a facility notifies the survey agency of a change in organization or management, review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g., written policies and procedures, personnel qualifications and agreements. If changes in a facility's organization and management are significant and raise questions of its continued compliance, determine, through a survey, whether certain changes have caused a decline in quality of care furnished by a SNF or NF. Collect information about the changes in the facility's organization and management on the Ownership and Control Interest Disclosure Statement (HCFA-1513). (See Exhibit 6.)

VIII.CONFIDENTIALITY AND RESPECT FOR RESIDENT PRIVACY

Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. Use the resident identifier (e.g., a code number the survey team has assigned to each resident in the

sample) on the HCFA-2567 in place of the resident's name, which should never be used on the HCFA-2567.

When communicating to the facility about substandard quality of care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, medication error, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order are examples of practices that can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is more likely to be obtained through resident and family interviews. Do not identify residents or family members providing this information without their permission.

Your notes and worksheets contain pre-decisional information and are, therefore, not required to be disclosed to the facility at the time of the survey. However, once the HCFA-2567 has been written, portions of the worksheets explaining the findings reported on the HCFA-2567 may become subject to release under the Freedom of Information Act (FOIA). Information on the worksheets that was not subsequently used as a basis for writing a deficiency remains pre-decisional and is exempt from disclosure. That information would have to be deleted, according to FOIA guidelines, before the worksheets could be released.

The requirements of the FOIA apply only to those documents held by the Federal government. They do not apply to State or local governments. Therefore, surveyor worksheets held by the State are subject to State disclosure laws only.

IX. INFORMATION TRANSFER

In conjunction with conducting surveys, the State should provide information to the facility about care and regulatory topics that would be useful to the facility for understanding and applying best practices in the care and treatment of long term care residents.

This information exchange is not a consultation with the facility, but is a means of disseminating information that may be of assistance to the facility in meeting long term care requirements. States are not liable, nor are they to be held accountable if training which occurs during information transfer does not "correct" problems at the facility.

Performance of the function is at the discretion of the State and can be performed at various times, including during the standard survey, during follow-up or complaint surveys, during other conferences or workshops or at another time mutually agreeable to the survey agency and the facility. The time allotted for this information transfer should not usually exceed one hour. In no instance should the information transfer delay the survey process.

The Health Care Financing Administration, in cooperation with State survey agencies and consumer and provider groups, will develop and provide packages of training materials suitable for use in this activity.

X. ADDITIONAL PROCEDURES FOR MEDICARE PARTICIPATING LONG TERM CARE FACILITIES

Medicare-participating long term care facilities are obligated to inform Medicare beneficiaries about specific rights related to billing, and to submit bills to the Medicare intermediary when requested by the beneficiary. In a Medicare-certified long term care facility, verify compliance with these requirements. Listed below are the requirements and the survey process you must follow:

o If a Medicare SNF provider believes, on admission, or during a resident's stay, that Medicare will not pay for skilled nursing or specialized rehabilitative services, the facility must inform the resident or his/her legal representative in writing why these specific services may not be covered. The facility must use the mandatory denial notice found in §358 of the Skilled Nursing Facility Manual, and keep a copy of this uniform denial notice on file. Failure to give notice using the uniform facility denial notice or to submit the bill, if requested by a resident, may constitute a violation of the facility's provider agreement to submit information to the intermediary. (See 42 CFR 489.21(b).)

o The facility is also required to inform each Medicare resident of his or her right to request that the facility submit the bill to the Medicare payor (demand bill). If the resident requests that the bill be submitted to the intermediary or carrier for a Medicare decision, then evidence that the submission has occurred should also appear in the resident's record. The facility must not charge the resident while the demand bill is under review by the Medicare payor.

o During the entrance conference, obtain a list of Medicare residents who requested demand bills in the past 6 months. From this list, randomly select one resident's file to determine if the bill was properly submitted to the intermediary. In addition, draw a sample of all residents in the facility.

The number sampled for this procedure must be equal to the sample size selected for quality of life resident interviews. Use the Sample Selection Table (see page 19) to obtain the correct sample size. Check to determine that the denial letters included appropriate notice information and that bills were submitted upon request. Review billing records for the last 6 months for each resident selected. During resident interviews use the following probes:

o [Individual] Do you know what things or services you pay for out of your own pocket? Who handles the payment for these items?

o [Individual] How do you find out how much these services or things cost?

o [Individual] Tell me how you find out what you have to pay for here?

o [Individual] When you receive a bill to pay for services out-of-pocket, does the facility explain why it believes Medicare will not pay for the services? Does the facility let you know that, if you disagree, you can have a bill submitted to Medicare?

o [Individual] Have you received a bill which you asked to have submitted to Medicare or your insurance company? How has the facility helped you or discouraged you from submitting the bill?

o [Group] Have there been any changes in the charges since you've been here? How do you find out about these changes?

o [Group] How does the facility give you information about your Medicare or Medicaid benefits?

o [Group] Did you or your family receive an explanation of any charges or monthly bills?

If residents are not clear about the scope of services they are entitled to, or the additional services provided by the facility and the cost of these services, or their right to have bills submitted to Medicare, and/or you identify problems during the review of resident records, either in the uniform notice or the bill submittal process, interview administrative staff to determine how the facility informs

residents about their Medicare and Medicaid benefits, the non-covered services the facility provides, and the facility's charges for these services. Review additional resident records to assure the facility is using the uniform facility denial notice.

If the facility is in violation of the provider agreement with respect to resident billing requirements, cite tag F492, 42 CFR 483.75(b) Compliance with Federal, State and local laws and professional standards. If the facility is in violation of notice requirements, cite tag F156.

When reviewing facility plans of correction, if a deficiency is noted with respect to billing procedures, it may be appropriate to expect submission of past claims.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F150	§483.5 Definitions. For purposes of this subpart--"Facility" means, a skilled nursing facility (SNF) or a nursing facility (NF) which meets the requirements of sections 1819 or 1919(a), (b), (c), and (d) of the Act. "Facility" may include a distinct part of an institution specified in §440.40 of this chapter, but does not include an institution for the mentally retarded or persons with related conditions described in §440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the "facility" is always the entity which participates in the program, whether that entity is comprised of all of, or a distinct part of a larger institution. For Medicare, a SNF (see section 1819(a)(1)), and for Medicaid, a NF (see section 1919(a)(1)) may not be an institution for mental diseases as defined in §435.1009.	Guidelines: §483.5 The following are the statutory definitions at §§1819(a) and 1919(a) of the Social Security Act (the Act) for a SNF and a NF: "Skilled nursing facility" is defined as an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases; has in effect a transfer agreement (meeting the requirements of §1861(1)) with one or more hospitals having agreements in effect under §1866; and meets the requirements for a SNF described in subsections (b), (c), and (d) of this section. "Nursing facility" is defined as an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities, and is not primarily for the care and treatment of mental diseases; has in effect a transfer agreement (meeting the requirements of §1861(1)) with one or more hospitals having agreements in effect under §1866; and meets the requirements for a NF described in subsections (b), (c), and (d) of this section. If a provider does not meet one of these definitions, it cannot be certified for participation in the Medicare and/or Medicaid programs. NOTE: IF THE SURVEY TEAM FINDS SUBSTANDARD CARE IN §§483.13, 483.15, OR 483.25, FOLLOW THE INSTRUCTIONS FOR PARTIAL EXTENDED OR EXTENDED SURVEYS.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§483.10 Resident rights. The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:	Guidelines: §483.10 All residents in long term care facilities have rights guaranteed to them under Federal and State law. Requirements concerning resident rights are specified in §§483.10, 483.12, 483.13, and 483.15. Section 483.10 is intended to lay the foundation for the remaining resident's rights requirements which cover more specific areas. These rights include the resident's right to: o Exercise his or her rights (§483.10(a)); o Be informed about what rights and responsibilities he or she has (§483.10(b)); o If he or she wishes, have the facility manage his personal funds (§483.10(c)); o Choose a physician and treatment and participate in decisions and care planning (§483.10(d)); o Privacy and confidentiality (§483.10(e)); o Voice grievances and have the facility respond to those grievances (§483.10(f)); o Examine survey results (§483.10(g)); o Work or not work (§483.10(h)); o Privacy in sending and receiving mail (§483.10(i)); o Visit and be visited by others from outside the facility (§483.10(j)); o Use a telephone in privacy (§483.10(k)); o Retain and use personal possessions (§483.10(1)) to the maximum extent that space and safety permit; o Share a room with a spouse, if that is mutually agreeable (§483.10(m)); o Self-administer medication, if the interdisciplinary care planning team determines it is safe (§483.10(n)); and o Refuse a transfer from a distinct part, within the institution (§483.10(o)). A facility must promote the exercise of rights for each resident, including any who face barriers (such as communication problems, hearing problems and cognition limits) in the exercise of these rights. A resident, even though determined to be incompetent, should be able to assert these rights based on his or her degree of capability.
F151	(a) Exercise of rights. (1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.	Guidelines: §483.10(a)(1) Exercising rights means that residents have autonomy and choice, to the maximum extent possible, about how they wish to live their everyday lives and receive care, subject to the facility's rules, as long as those rules do not violate a regulatory requirement.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F151 Cont.	(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.	Intent: §483.10(a)(2) This regulation is intended to protect each resident in the exercise of his or her rights. Guidelines: §483.10(a)(2) The facility must not hamper, compel, treat differentially, or retaliate against a resident for exercising his/her rights. Facility behaviors designed to support and encourage resident participation in meeting care planning goals as documented in the resident assessment and care plan are not interference or coercion. Examples of facility practices that may limit autonomy or choice in exercising rights include reducing the group activity time of a resident trying to organize a residents' group; requiring residents to seek prior approval to distribute information about the facility; discouraging a resident from hanging a religious ornament above his or her bed; singling out residents for prejudicial treatment such as isolating residents in activities; or purposefully assigning inexperienced aides to a resident with heavy care needs because the resident and/or his/her representatvive, exercised his/her rights. Procedures: §483.10(a)(2) Pay close attention to resident or staff remarks and staff behavior that may represent deliberate actions to promote or to limit a resident's autonomy or choice, particularly in ways that affect independent functioning. Because reprisals may indicate abuse, if the team determines that a facility has violated this requirement through reprisals taken against residents, then further determine if the facility has an effective system to prevent the neglect and abuse of residents. (§483.13(c), F224-F225.)
F152	(3) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf. (4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.	Guidelines: §483.10(a)(3) and (4) When reference is made to "resident" in the Guidelines, it also refers to any person who may, under State law, act on the resident's behalf when the resident is unable to act for himself or herself. That person is referred to as the resident's surrogate or representative. If the resident has been formally declared incompetent by a court, the surrogate or representative is whoever was appointed by the court - a guardian, conservator, or committee. The facility should verify that a surrogate or representative has the necessary authority. For example, a court-appointed conservator might have the power to make financial decisions, but not health care decisions. A resident may wish to delegate decision-making to specific persons, or the resident and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, and to the maximum extent practicable, the facility must respect the resident's wishes and follow that process.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F152 Cont.		The rights of the resident that may be exercised by the surrogate or representative include the right to make health care decisions. However, the facility may seek a health care decision (or any other decision or authorization) from a surrogate or representative only when the resident is unable to make the decision. If there is a question as to whether the resident is able to make a health care decision, staff should discuss the matter with the resident at a suitable time and judge how well the resident understands the information. In the case of a resident who has been formally declared incompetent by a court, lack of capacity is presumed. Notwithstanding the above, if such a resident can understand the situation and express a preference, the resident should be informed and his/her wishes respected to the degree practicable. Any violations with respect to the resident's exercise of rights should be cited under the applicable tag number. The involvement of a surrogate or representative does not automatically relieve a facility of its duty to protect and promote the resident's interests. For example, a surrogate or representative does not have the right to insist that a treatment be performed that is not medically appropriate, and the right of a surrogate or representative to reject treatment may be subject to State law limits. Procedures: §483.10(a)(3) and (4) Determine as appropriate if the rights of a resident who has been adjudged incompetent or who has a representative acting on his/her behalf to help exercise his/her rights are exercised by the legally appointed individual.
Refer to F156	(b) Notice of rights and services. (1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under §1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such	Intent: §483.10(b)(1) This requirement is intended to assure that each resident know his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, as appropriate during the resident's stay, and when the facility's rules change. Guidelines: §483.10(b)(1) "In a language that the resident understands" is defined as communication of information concerning rights and responsibilities that is clear and understandable to each resident, to the extent possible considering impediments which may be created by the resident's health and mental status. If the resident's knowledge of English or the predominant language of the facility is inadequate for comprehension, a means to communicate the information concerning rights and responsibilities in a language familiar to the resident must be available and implemented. For foreign languages

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	information, and any amendments to it, must be acknowledged in writing;	commonly encountered in the facility locale, the facility should have written translations of its statements of rights and responsibilities, and should make the services of an interpreter available. In the case of less commonly encountered foreign languages, however, a representative of the resident may sign that he or she has explained the statement of rights to the resident prior to his/her acknowledgement of receipt. For hearing impaired residents who communicate by signing, the facility is expected to provide an interpreter. Large print texts of the facility's statement of resident rights and responsibilities should also be available. "Both orally and in writing," means if a resident can read and understand written materials without assistance, an oral summary, along with the written document, is acceptable. Any time State or Federal laws relating to resident rights or facility rules change during the resident's stay in the facility, he/she must promptly be informed of these changes. "All rules and regulations" relates to facility policies governing resident conduct. A facility cannot reasonably expect a resident to abide by rules he or she has never been told about. Whatever rules the facility has formalized, and by which it expects residents to abide, should be included in the statement of rights and responsibilities.
F153	(2) The resident or his or her legal representative has the right-- (i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and (ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.	Guidelines: §483.10(b)(2) An oral request is sufficient to produce the current record for review. In addition to clinical records, the term "records" includes all records pertaining to the resident, such as trust fund ledgers pertinent to the resident and contracts between the resident and the facility. "Purchase" is defined as a charge to the resident for photocopying. If State statute has defined the "community standard" rate, facilities should follow that rate. In the absence of State statute, the "cost not to exceed the community standard" is that rate charged per copy by organizations such as the public library, the Post Office or a commercial copy center, which would be selected by a prudent buyer in addition to the cost of the clerical time needed to photocopy the records. Additional fees for locating the records or typing forms/envelopes may not be assessed.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F154	(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;	Guidelines: §483.10(b)(3) "Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand. This includes minimizing use of technical jargon in communicating with the resident, having the ability to communicate in a foreign language and the use of sign language or other aids, as necessary. (See §483.10(d)(3), for the right of the resident to plan care and treatment.) Procedures: §483.10(b)(3) Look, particularly during observations and record reviews, for on-going efforts on the part of facility staff to keep residents informed. Look for evidence that information is communicated in a manner that is understandable to residents and communicated at times it could be most useful to residents, such as when they are expressing concerns, or raising questions, as well as on an on-going basis.
F155	(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and	Guidelines: §483.10(b)(4) "Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms. "Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy, that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research. "Advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law relating to the provision of health care when the individual is incapacitated. As provided under State law, a resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes. A facility may not transfer or discharge a resident for refusing treatment unless the criteria for transfer or discharge are met. (See §483.12(a)(1) and (2).)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F155 Cont.		If the resident is unable to make a health care decision, a decision by the resident's surrogate or representative to forego treatment may, subject to State law, be equally binding on the facility. The facility should determine exactly what the resident is refusing and why. To the extent the facility is able, it should address the resident's concern. For example, a resident requires physical therapy to learn to walk again after sustaining a fractured hip. The resident refuses therapy. The facility is expected to assess the reasons for this resident's refusal, clarify and educate the resident as to the consequences of refusal, offer alternative treatments, and continue to provide all other services. If a resident's refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. A resident's refusal of treatment does not absolve a facility from providing a resident with care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being in the context of making that refusal. The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining residents' permission. Procedures: §483.10(b)(4) If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? In this regard, §483.75(c) Relationship to Other HHS Regulations applies (i.e., the facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research). See §483.10(b)(8) F156 with respect to the advance directive requirement.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F156	(5) The facility must-- (i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of-- (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and (ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section. (6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.	Guidelines: §483.10(b)(5) and (6) Residents should be told in advance when changes will occur in their bills. Providers must fully inform the resident of services and related changes. "Periodically" means that whenever changes are being introduced that will affect the residents liability and whenever there are changes in services. A Medicare beneficiary who requires services upon admission that are not covered under Medicare may be required to submit a deposit provided the notice provisions of §483.10(b)(6), if applicable, are met. Procedures: §483.10(b)(5) and (6) See §483.10(c)(8) for those items and services that must be included in payment under skilled nursing and nursing facility benefits.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F156 Cont.	(7) The facility must furnish a written description of legal rights which includes-- (i) A description of the manner of protecting personal funds, under paragraph (c) of this section; (ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple's non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in his or her process of spending down to Medicaid eligibility levels; (iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and (iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, and misappropriation of resident property in the facility.	Guidelines: §483.10(b)(7) "The protection and advocacy network" refers to the system established to protect and advocate the rights of individuals with developmental disabilities specified in the Developmental Disabilities Assistance and Bill of Rights Act, and the protection and advocacy system established under the Protection and Advocacy for Mentally Ill Individuals Act. Procedures: §483.10(b)(7) At the Entrance Conference, request a copy of the written information that is provided to residents regarding their rights and review it to determine if it addresses the specified requirements. Additional requirements that address the implementation of these rights are cross-referenced below.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F156 Cont.	(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law.	Guidelines: §483.10(b)(8) This provision applies to residents admitted on or after December 1, 1991. 42 CFR 489.102 specifies that at the time of admission of an adult resident, the facility must: o Provide written information concerning his/her rights under State law (whether or not statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives; o Document in the resident's medical record whether or not the individual has executed an advance directive; o Not condition the provision of care or discriminate against an individual based on whether or not the individual has executed an advance directive; o Ensure compliance with requirements of State law regarding advance directives; o Provide for educating staff regarding the facility's policies and procedures on advance directives; and o Provide for community education regarding the right under State law (whether or not recognized by the courts of the State) to formulate an advance directive and the facility's written policies and procedures regarding the implementation of these rights, including any limitations the facility may have with respect to implementing this right on the basis of conscience. The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows the provider to conscientiously object. (See §483.10(b)(4), F155.) The sum total of the community education efforts must include a summary of the State law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audio tapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience. Procedures: §483.10(b)(8) During Resident Review, review the records of two selected sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements. o Determine to what extent the facility educates its staff regarding advance directives. o Determine to what extent the facility provides education for the community regarding one's rights under State law to formulate advance directives.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F156 Cont.	(9) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.	Guidelines: §483.10(b)(9) "Physician responsible for his or her care" is defined as the attending or primary physician or clinic, whichever is responsible for managing the resident's medical care, and excludes other physicians whom the resident may see from time to time. When a resident has selected an attending physician, it is appropriate for the facility to confirm that choice when complying with this requirement. When a resident has no attending physician, it is appropriate for the facility to assist residents to obtain one in consultation with the resident and subject to the resident's right to choose. (See §483.10(d)(1), F163.) If a facility uses the services of a clinic or similar arrangement, it may be sufficient for residents to have the name and contact information for the primary physician and/or a central number for the clinic itself.
	(10) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.	Guidelines: §483.10(b)(10) To fulfill this requirement, the facility may use written materials issued by the State Medicaid agency and the Federal government relating to these benefits. Facilities may fulfill their obligation to orally inform residents or applicants for admission about how to apply for Medicaid or Medicare by assisting them in contacting the local Social Security Office or the local unit of the State Medicaid agency. Nursing facilities are not responsible for orally providing detailed information about Medicare and Medicaid eligibility rules. "Refunds for previous payments" refers to refunds due as a result of Medicaid and Medicare payments when eligibility has been determined retroactively. As part of determining Medicaid eligibility, at the time of admission, a married couple has the right to request and have the appropriate State agency assess the couple's resources.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F157	(11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is-- (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention; (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications); (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or (D) A decision to transfer or discharge the resident from the facility as specified in §483.12(a). (ii) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is-- (A) A change in room or roommate assignment as specified in §483.15(e)(2); or	Guidelines: §483.10(b)(11) For purposes of §483.10(b)(11)(i)(B), life-threatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II pressure sore, onset or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before). In the case of a competent individual, the facility must still contact the resident's physician and notify interested family members, if known. That is, a family that wishes to be informed would designate a member to receive calls. Even when a resident is mentally competent, such a designated family member should be notified of significant changes in the resident's health status because the resident may not be able to notify them personally, especially in the case of sudden illness or accident. The requirements at §483.10(b)(1) require the facility to inform the resident of his/her rights upon admission and during the resident's stay. This includes the resident's right to privacy (§483.10(e), F164). If, after being informed of the right to privacy, a resident specifies that he/she wishes to exercise this right and not notify family members in the event of a significant change as specified at this requirement, the facility should respect this request, which would obviate the need to notify the resident's interested family member or legal representative, if known. If a resident specifies that he/she does not wish to exercise the right to privacy, then the facility is required to comply with the notice of change requirements. In the case of a resident who is incapable of making decisions, the representative would make any decisions that have to be made, but the resident should still be told what is happening to him or her. In the case of the death of a resident, the resident's physician is to be notified immediately in accordance with State law. The failure to provide notice of room changes could result in an avoidable decline in physical, mental, or psychosocial well-being.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F157 Cont.	(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section. (iii) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.	
	(c) Protection of Resident Funds.	
F158	(1) The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.	Guidelines: §483.10(c)(1) through (3) This requirement is intended to assure that residents who have authorized the facility in writing to manage any personal funds have ready and reasonable access to those funds. If residents choose to have the facility manage their funds, the facility may not refuse to handle these funds, but is not responsible for knowing about assets not on deposit with it.
F159	(2) Management of personal funds. Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3)-(8) of this section. (3) Deposit of funds. (i) Funds in excess of $50. The facility must deposit any residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the	Placement of residents' personal funds of less than $50.00 ($100.00 for Medicare residents) in an interest bearing account is permitted. Thus, a facility may place the total amount of a resident's funds, including funds of $50.00 ($100.00 for Medicare residents) or less, into an interest-bearing account. The law and regulations are intended to assure that residents have access to $50.00 ($100.00 for Medicare residents) in cash within a reasonable period of time, when requested. Requests for less than $50.00 ($100.00 for Medicare residents) should be honored within the same day. Requests for $50.00 ($100.00 for Medicare residents) or more should be honored within three banking days. Although the facility need not maintain $50.00 ($100.00 for Medicare residents) per resident on its premises, it is expected to maintain amounts of petty cash on hand that may be required by residents. If pooled accounts are used, interest must be prorated per individual on the basis of actual earnings or end-of-quarter balance. Residents should have access to petty cash on an ongoing basis and be able to arrange for access to larger funds. "Hold, safeguard, manage and account for," means that the facility must act as fiduciary of the resident's funds and report at least quarterly on the status of these funds in a clear and understandable manner. Managing the resident's financial affairs includes money that an individual gives to the facility for the sake of

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F159 Cont.	Facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) (ii) Funds less than $50. The facility must maintain a resident's personal funds that do not exceed $50 in a non-interest bearing account, interest-bearing account, or petty cash fund. NOTE: The Social Security Amendments of 1994 amended §1819(c)(6)(B)(i) to raise the limit from $50.00 to $100.00 for the minimum amount of resident funds that facilities must entrust to an interest bearing account. This increase applies only to Medicare SNF residents. While a facility may continue to follow a minimum of $50.00, the regulations do not require it.	providing a resident with a noncovered service (such as a permanent wave). It is expected that in these instances, the facility will provide a receipt to the gift giver and retain a copy. "Interest bearing" means a rate of return equal to or above the passbook savings rate at local banking institutions in the area. Although the requirements are silent about oral requests by residents to have a facility hold personal funds, under the provisions regarding personal property (§483.10(l)), and misappropriation of property (§483.13(c)), residents may make oral requests that the facility temporarily place their funds in a safe place, without authorizing the facility to manage those funds. The facility has the responsibility to implement written procedures to prevent the misappropriation of these funds. If you determine potential problems with funds through interviews, follow-up using the following procedures as appropriate: If the facility does not have written authorization to handle resident's funds, but is holding funds for more than a few days, determine if the facility is managing these funds without written authorization. There must be written authorization for the facility to be in compliance with this requirement. To assure that facilities are not using oral requests by residents as a way to avoid obtaining written authorization to hold, manage, safeguard and account for resident's funds, make sure that: o There is a written declaration by the resident that the funds are being held for no more than a few days by the facility at the resident's request; o These funds are not held for more than a few days; and o The facility provides the resident a receipt for these funds and retains a copy for its records. Review the administrative or business file and the bookkeeping accounts of residents selected for a comprehensive review who have authorized the facility to handle their personal funds. o Are residents' funds over $50.00 ($100.00 for Medicare residents) or, at the facility's option, all resident funds, in an interest bearing account(s)? o What procedure was followed when residents requested their funds? o How long does it take for residents to receive: (a) petty cash allotments; (b)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F159 Cont.	(4) Accounting and records. The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf. (i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident. (ii) The individual financial record must be available through quarterly statements and on request to the resident or his or her legal representative.	funds needing to be withdrawn from bank accounts? o Were limits placed on amounts that could be withdrawn? If yes, was the reason based on resident care needs or facility convenience? o Are funds records treated with privacy as required at F164? NOTE: Banks may charge the resident a fee for handling their funds. Facilities may not charge residents for managing residents' funds because the services are covered by Medicare or Medicaid. If problems are identified, review also §483.10(b(7), F156. Monies due residents should be credited to their respective bank accounts within a few business days. Guidelines: §483.10(c)(4) This requirement constitutes the overall response of the facility to the resident's right to have the facility manage the resident's funds. "Generally accepted accounting principles" means that the facility employs proper bookkeeping techniques, by which it can determine, upon request, the amount of individual resident funds and, in the case of an interest bearing account, how much interest these funds have earned for each resident, as last reported by the banking institution to the facility. Proper bookkeeping techniques would include an individual ledger card, ledger sheet or equivalent established for each resident on which only those transactions involving his or her personal funds are recorded and maintained. The record should have information on when transactions occurred, what they were, as well as maintain the ongoing balance for every resident. Anytime there is a transaction the resident should be given a receipt and the facility retains a copy. Monies due residents should be credited to their respective bank accounts within a few business days.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F159 Cont.	(5) Notice of certain balances. The facility must notify each resident that receives Medicaid benefits-- (i) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and (ii) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.	"Quarterly statements," are to be provided in writing to the resident or the resident's representative within 30 days after the end of the quarter. Guidelines: §483.10(c)(5) The Social Security District Office can provide you with information concerning current SSI resource limits. Procedures: §483.10(c)(5) If problems are identified for sampled residents who are Medicaid recipients, review financial records to determine if their accounts are within $200.00 of the SSI limit. If there are sampled residents in this situation, ask them or their representatives if they have received notice.
F160	(6) Conveyance upon death. Upon the death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.	Procedures: §483.10(c)(6) As part of closed records review, determine if within 30 days of death, the facility conveyed the deceased resident's personal funds and a final accounting to the individual or probate jurisdiction administering the individual's estate as provided by State law.
F161	(7) Assurance of financial security. The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.	Guidelines: §483.10(c)(7) A surety bond is an agreement between the principal (the facility), the surety (the insurance company), and the obligee (depending on State law, either the resident or the State acting on behalf of the resident), wherein the facility and the insurance company agree to compensate the resident (or the State on behalf of the resident) for any loss of residents' funds that the facility holds, safeguards, manages, and accounts for.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F161 Cont.		The purpose of the surety bond is to guarantee that the facility will pay the resident (or the State on behalf of the resident) for losses occurring from any failure by the facility to hold, safeguard, manage, and account for the residents' funds, i.e., losses occurring as a result of acts or errors of negligence, incompetence or dishonesty. Unlike other types of insurance, the surety bond protects the obligee (the resident or the State), not the principal (the facility), from loss. The surety bond differs from a fidelity bond, which covers no acts or errors of negligence, incompetence or dishonesty. The surety bond is the commitment of the facility in an objective manner to meet the standard of conduct specified in §483.10(c)(2), that the facility will hold, safeguard, manage and account for the funds residents have entrusted to the facility. The facility assumes the responsibility to compensate the obligee for the amount of the loss up to the entire amount of the surety bond. Reasonable alternatives to a surety bond must: o Designate the obligee (depending on State law, the resident individually or in aggregate, or the State on behalf of each resident) who can collect in case of a loss; o Specify that the obligee may collect due to any failure by the facility, whether by commission, bankruptcy, or omission, to hold, safeguard, manage, and account for the residents' funds; and o Be managed by a third party unrelated in any way to the facility or its management. The facility cannot be named as a beneficiary. Self-insurance is not an acceptable alternative to a surety bond. Likewise, funds deposited in bank accounts protected by the Federal Deposit Insurance Corporation, or similar entity, also are not acceptable alternatives. Procedures: §483.10(c)(7) As part of Phase 2, if your team has any concerns about residents' funds, check the amount of the surety bond to make sure it is at least equal to the total amount of residents' funds, as of the most recent quarter.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F161 Cont.		If the State survey agency determines that individual circumstances associated with a facility's surety bond or its alternative are such that the survey agency cannot determine whether or not the facility is in compliance with the requirements at §483.10(c)(7), then it would be appropriate to make the referral to the State's fiscal department. If a corporation has a surety bond that covers all of its facilities, there should be a separate review of the corporation's surety bond by the appropriate State agency, such as the State's fiscal department, to ensure that all the residents in the corporation's facilities within the State are covered against any losses due to acts or errors by the corporation or any of its facilities. The focus of the review should be to ensure that if the corporation were to go bankrupt or otherwise cease to operate, the funds of the residents in the corporation's facilities would be protected.
F162	(8) Limitation or charges to personal funds. The facility may not impose a charge against the personal funds of a resident for any item or services for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)	Intent: §483.10(c)(8) The intent of this requirement is to specify that facilities not charge residents for items and services for which payment is made under Medicare or Medicaid. Guidelines: §483.10(c)(8) The facility may charge the resident the difference for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or co-payment required by the plan to be paid by the individual.) If a State plan does not cover an item or service, such as eyeglasses, the resident may purchase that item or service out of his/her funds. See §483.15(g), F250 for the facility's responsibility to assist the resident in obtaining those services. §483.10(c)(8)(i)(E): Prescription drugs are part of the pharmaceutical services that facilities are required to provide. (See §483.25(l) and (m), and §483.60.) However, at times, a resident needs a medical service that is recognized by State law, but not covered by the State plan. Such a medical service includes a prescription drug that is not on the State's formulary or that exceeds the number of medications covered by Medicaid. It may also include prescription eyeglasses or dentures. If a resident needs a recognized medical service over what is allowed by the State plan, the resident has the right under the Medicaid statute to spend his/her income on that service. If the service is more than what Medicaid pays, the resident may deduct the actual cost of

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F162 Cont.	(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities may not charge a resident for the following categories of items and services: (A) Nursing services as required at §483.30 of this subpart. (B) Dietary services as required at §483.35 of this subpart. (C) An activities program as required at §483.15(f) of this subpart. (D) Room/bed maintenance services. (E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing, and basic personal laundry.	the service from the Medicaid share of the cost. The facility must assist the resident in exercising his or her right to the uncovered medical expense deduction and may not charge the resident for such services. "Hair hygiene supplies" refers to comb, brush, shampoos, trims and simple hair cuts provided by facility staff as part of routine grooming care. Hair cuts, permanent waves, hair coloring, and relaxing performed by barbers and beauticians not employed by a facility are chargeable. "Nail hygiene services" refers to routine trimming, cleaning, filing, but not polishing of undamaged nails, and on an individual basis, care for ingrown or damaged nails. "Basic personal laundry" does not include dry cleaning, mending, washing by hand, or other specialty services that need not be provided. A resident may be charged for these specialty services if he or she requests and receives them. §483.10(c)(8)(ii)(I) Social events. Facilities are required by §483.15(f) to provide an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and physical, mental, and psychosocial well-being of each resident, and cannot charge residents for these services, whether they occur at the facility or off-site. Resident funds should not be charged for universal items such as bookmobile services or local newspaper subscriptions intended for use by more than one resident. However, if a resident requests and attends a social event or entertainment that is not part of the activities assessment and care plan for that resident, a facility may charge that resident's account only for actual expenses. Further, because of expenses associated with transportation, escorts and other related costs, a resident may be charged for actual expenses for an event or entertainment he or she requests and attends that may be free to the public. §483.10(c)(8)(ii)(L) Specially prepared food. A resident may refuse food usually prepared and food substitutions of similar nutritive value because of personal, religious, cultural, or ethnic preference. If the resident requests and receives food that is either not commonly purchased by the facility or easily prepared, then the facility may charge the resident. For example, the facility may charge the resident's account for specially prepared food if the facility has a restricted diet policy and notified the resident on admission of the fact, in accordance with §483.10(b). The facility may not charge the resident's account for specially prepared foods that are required by the physician's order of a therapeutic diet. If a facility changes its menu so that the menu no longer reflects the food preferences of residents, see F165, F242 and F243 to determine compliance with these requirements.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F162 Cont.	(F) Medically-related social services as required at §483.15(g) of this subpart. (ii) Items and services that may be charged to residents' funds. Listed below are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid: (A) Telephone; (B) Television/radio for personal use; (C) Personal comfort items, including smoking materials, notions and novelties, and confections; (D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare; (E) Personal clothing; (F) Personal reading matter; (G) Gifts purchased on behalf of a resident; (H) Flowers and plants; and (I) Social events and entertainment offered outside the	§483.10(c)(8)(iii) Requests for items and services. A facility may not charge a resident or the resident's representative for items and services that are not requested by the resident or representative, whether or not the item or services is requested by a physician. The item or service ordered by the physician should fit in with the resident's care plan. Procedures: §483.10(c)(8) As appropriate during Phase 2 of the survey, review the written information given to Medicare/Medicaid eligible residents and family members on admission that notifies them of the items and services that are covered under Medicare or the State plan. Review a sample of residents' monthly statements to ensure that personal funds are not used to pay for covered services. If charges found on monthly statements indicate that residents may have paid for covered items or services, determine if these items or services are over and above what is paid by Medicare or Medicaid. If, through observations or interviews of residents selected for comprehensive or focused review, the team determines that families or residents hire sitters, and/or that a large number of residents or families are paying for outside food, determine if these practices reflect inadequate staffing and/or food.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F162 Cont.	scope of the activities program, provided under §483.15(f) of this subpart. (J) Noncovered special care services such as privately hired nurses or aides. (K) Private room, except when therapeutically required (for example, isolation for infection control). (L) Specially prepared or alternative food requested instead of the food generally prepared by the facility, as required by §483.35 of this subpart. (iii) Requests for items and services. (A) The facility must not charge a resident (or his or her representative) for any item or service not requested by the resident. (B) The facility must not require a resident (or his or her representative) to request any item or service as a condition of admission or continued stay. (C) The facility must inform the resident (or his or her representative) requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(d) Free Choice. The resident has the right to-	Guidelines: §483.10(d)(1)
F163	(1) Choose a personal attending physician;	The right to choose a personal physician does not mean that the physician must or will serve the resident, or that a resident must designate a personal physician. If a physician of the resident's choosing fails to fulfill a given requirement, such as §483.25(l)(1), Unnecessary drugs, §483.25(l)(2), Antipsychotic drugs, or §483.40 frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own physicians. For example, if a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his or her choice in finding another physician. Before consulting an alternate physician, one mechanism to alleviate a possible problem could involve the facility's utilization of a peer review process for cases which cannot be satisfactorily resolved by discussion between the medical director and the attending physician. Only after a failed attempt to work with the attending physician or mediate differences in delivery of care should the facility request an alternate physician when requested to do so by the resident or when the physician will not adhere to the regulations. If it is a condition for admission to a continuing care retirement center, the requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges at the retirement center. A resident in a distinct part of a general acute care hospital can choose his/her own physician, unless the hospital requires that physicians with residents in the distinct part have hospital admitting privileges. If this is so, the resident can choose his/her own physician, but cannot have a physician who does not have hospital admitting privileges. If residents appear to have problems in choosing physicians, determine how the facility makes physician services available to residents.
Refer to F154	(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and	Guidelines: §483.10(d)(2) "Informed in advance" means that the resident receives information necessary to make a health care decision, including information about his/her medical condition and changes in medical condition, about the benefits and reasonable risks of the treatment, and about reasonable available alternatives.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Refer to F280	(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.	Guidelines: §483.10(d)(3) "Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident's right to participate in care planning and to refuse treatment are covered in §§483.20(d)(2) and 483.10(b)(4). A resident whose ability to make decisions about care and treatment is impaired, or a resident who has been formally declared incompetent by a court, should, to the extent practicable, be kept informed and be consulted on personal preferences. Whenever there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate. Procedures: §483.10(d)(3) Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes (e.g., ask residents or their representatives during interviews).
F164	(e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.	Guidelines: §483.10(e) "Right to privacy" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include full visual, and, to the extent desired, for visits or other activities, auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes. For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F164 Cont.	(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident; (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility; (3) The resident's right to refuse release of personal and clinical records does not apply when-- (i) The resident is transferred to another health care institution; or (ii) Record release is required by law.	With the exception of the explicit requirement for privacy curtains in all initially certified facilities (see §483.70(d)(1)(v)), the facility is free to innovate to provide privacy for its residents, as exemplified in the preceding paragraph. This may, but need not, be through the provision of a private room. Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services. Personal and clinical records include all types of records the facility might keep on a resident, whether they are medical, social, fund accounts, automated or other. Additional guidelines on mail, visitation rights and telephone communication are addressed in §483.10(i), (j) and (k). See §483.70(d)(1)(iv) for full visual privacy around beds. Procedures: §483.10(e)(1) - (3) Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated (e.g., Resident #12 left without gown or bed covers and unattended), and where and when this occurred (e.g., 2B Corridor, 3:30 pm, February 25). If possible, identify the responsible party.
	(f) Grievances. A resident has the right to--	Intent: §483.10(f) The intent of the regulation is to support each resident's right to voice grievances (e.g., those about treatment, care, management of funds, lost clothing, or violation of rights) and to assure that after receiving a complaint/grievance, the facility actively seeks a resolution and keeps the resident appropriately apprised of its progress toward resolution.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F165	(1) Voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished; and	Guidelines: §483.10(f) "Voice grievances" is not limited to a formal, written grievance process but may include a resident's verbalized complaint to facility staff. "Prompt efforts...to resolve" include facility acknowledgment of complaint/grievances and actively working toward resolution of that complaint/grievance. If residents' responses indicate problems in voicing grievances and getting grievances resolved, determine how the facility deals with and makes prompt efforts to resolve resident complaints and grievances. o With permission, review resident council minutes. o Interview staff about how grievances are handled. o Interview staff about communication (to resident) of progress toward resolution of complaint/grievance. If problems are identified, also investigate compliance with §483.10(b)(7)(iii). Guidelines: §483.10(g)(1)-(2) "Results of the most recent survey" means the Statement of Deficiencies (HCFA-2567) and the Statement of Isolated Deficiencies generated by the most recent standard survey and any subsequent extended surveys, and any deficiencies resulting from any subsequent complaint investigation(s). "Made available for examination" means that survey results and approved plan of correction, if applicable, are available in a readable form, such as a binder, large print, or are provided with a magnifying glass, have not been altered by the facility unless authorized by the State agency, and are available to residents without having to ask a staff person. "Place readily accessible to residents" is a place (such as a lobby or other area frequented by most residents) where individuals wishing to examine survey results do not have to ask to see them.
F166	(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.	
	(g) Examination of survey results. A resident has the right to--	
F167	(1) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility. The facility must make the results available for examination in a place readily accessible to residents and must post a notice of their availability; and	
F168	(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F169	(h) Work. The resident has the right to-- (1) Refuse to perform services for the facility; (2) Perform services for the facility, if he or she chooses, when-- (i) The facility has documented the need or desire for work in the plan of care; (ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid; (iii) Compensation for paid services is at or above prevailing rates; and (iv) The resident agrees to the work arrangement described in the plan of care.	Guidelines: §483.10(h)(1)-(2) "Prevailing rate" is the wage paid to workers in the community surrounding the facility for essentially the same type, quality, and quantity of work requiring comparable skills. All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to discussion of medical appropriateness. As part of the plan of care, a therapeutic work assignment must be agreed to by the resident. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated. Procedures: §483.10(h)(1)-(2) Are residents engaged in what may be paid or volunteer work (e.g., doing housekeeping, doing laundry, preparing meals)? Pay special attention to the possible work activities of residents with mental retardation or mental illness. If you observe such a situation, determine if the resident is in fact performing work and, if so, is this work, whether voluntary or paid, described in the plan of care?
	(i) Mail. The resident has the right to privacy in written communications, including the right to--	
F170	(1) Send and promptly receive mail that is unopened; and	Guidelines: §483.10(i)(1)-(2) "Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours, except when there is no regularly scheduled postal delivery and pick-up service.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F171	(2) Have access to stationery, postage, and writing implements at the resident's own expense.	
F172	(j) Access and Visitation Rights. (1) The resident has the right and the facility must provide immediate access to any resident by the following: (i) Any representative of the Secretary; (ii) Any representative of the State; (iii) The resident's individual physician; (iv) The State long term care ombudsman (established under section 307 (a)(12) of the Older Americans Act of 1965); (v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act); (vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);	Guidelines: §483.10(j)(1) and (2) The facility must provide immediate access to any representative of the Secretary of the Department of Health and Human Services, the State, the resident's individual physician, the State long term care ombudsman, or the agencies responsible for the protection and advocacy of developmentally disabled or mentally ill individuals. The residents cannot refuse to see surveyors. Representatives of the Department of Health and Human Services, the State, the State ombudsman system, and protection and advocacy agencies for mentally ill and mentally retarded individuals are not subject to visiting hour limitations. Immediate family or other relatives are not subject to visiting hour limitations or other restrictions not imposed by the resident. However, the facility may try to change the location of visits to assist care giving or protect the privacy of other residents, if these visitation rights infringe upon the rights of other residents in the facility. For example, a resident's family visits in the late evening, which prevents the resident's roommate from sleeping. Non-family visitors must also be granted "immediate access" to the resident. The facility may place reasonable restrictions upon the exercise of this right such as reasonable visitation hours to facilitate care giving for the resident or to protect the privacy of other residents, such as requiring that visits not take place in the resident's room if the roommate is asleep or receiving care. An individual or representative of an agency that provides health, social, legal, or other services to the resident has the right of "reasonable access" to the resident, which means that the facility may establish guidelines regarding the timing or other circumstances of the visit, such as location. These guidelines must allow for ready access of residents to these services. Procedures: §483.10(j)(1) and (2) If you identify problems during interviews, determine how the facility ensures access to: o Representatives of the State; o Representatives of the U.S. Department of Health and Human Services; o The resident's individual physician; o Representatives of the State long-term care ombudsman;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F172 Cont.	(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and (viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident. (2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.	o Representatives of agencies responsible for protecting and advocating rights of persons with mental illness or developmental disabilities; o Family or relatives; and o Other visitors.
F173	(3) The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with State law.	Procedures: §483.10(j)(3) Ask the ombudsman if the facility allows him/her to examine residents' clinical records with the permission of the resident, and to the extent allowed by State law.
F174	(k) Telephone. The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.	Guidelines: §483.10(k) Telephones in staff offices or at nurses' stations do not meet the provisions of this requirement. Examples of facility accommodations to provide reasonable access to the use of a telephone without being overheard include providing cordless telephones or having telephone jacks in residents' rooms. "Reasonable access" includes placing telephones at a height accessible to residents who use wheelchairs and adapting telephones for use by the residents with impaired hearing.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Refer to F252	(l) Personal Property. The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.	Intent: §483.10(l) The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. Guidelines: §483.10(l) All residents' possessions, regardless of their apparent value to others, must be treated with respect, for what they are and for what they may represent to the resident. The right to retain and use personal possessions assures that the residents' environment be as homelike as possible and that residents retain as much control over their lives as possible. The facility has the right to limit the resident's exercise of this right on grounds of space and health or safety. Procedures: §483.10(l) If residents' rooms have few personal possessions, ask residents, families and the local ombudsman if: o Residents are encouraged to have and to use them; o The facility informs residents not to bring in certain items and for what reason; o Personal property is safe in the facility. Ask staff if the facility sets limits on the value of the property that residents may have in their possession or requires that residents put personal property in the facility's safe. See §483.15(h)(1) F252 for "use of his or her personal belongings to the extent possible, when the resident is not allowed to use his/her own personal possessions within the facility, or when the facility does not encourage the resident to retain and use his/her personal property.
F175	(m) Married couples. The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.	Guidelines: §483.10(m) The right of residents who are married to each other to share a room does not give a resident the right, or the facility the responsibility, to compel another resident to relocate to accommodate a spouse. The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose. If a married resident's spouse is admitted to the facility later and the couple want to share a room, the facility must provide a shared room as quickly as possible. However, a couple is not able to share a room if one of the spouses has a different payment source for which the facility is not certified (if the room is in a distinct part, unless one of the spouses elects to pay for his or her care).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F176	(n) Self-Administration of drugs. An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.	Guidelines: §483.10(n) If a resident requests to self-administer drugs, it is the responsibility of the interdisciplinary team to determine that it is safe for the resident to self-administer drugs before the resident may exercise that right. The interdisciplinary team must also determine who will be responsible (the resident or the nursing staff) for storage and documentation of the administration of drugs, as well as the location of the drug administration (e.g., resident's room, nurses' station, or activities room). Appropriate notation of these determinations should be placed in the resident's care plan. The decision that a resident has the ability to self-administer medication(s) is subject to periodic re-evaluation based on change in the resident's status. The facility may require that drugs be administered by the nurse or medication aide, if allowed by State law, until the care planning team has the opportunity to obtain information necessary to make an assessment of the resident's ability to safely self-administer medications. If the resident chooses to self-administer drugs, this decision should be made at least by the time the care plan is completed within seven days after completion of the comprehensive assessment. Medication errors occurring with residents who self-administer drugs should not be counted in the facility's medication error rate (see Guidelines for §483.25(m)), but should call into question the judgment made by the facility in allowing self-administration for those residents. Probes: §483.10(n) For residents selected for a comprehensive review or a focused review, as appropriate: o Does resident self-administer drugs? Which ones? How much? How often? o Does the care plan reflect self-administration?
F177	(o) Refusal of Certain Transfers. (1) An individual has the right to refuse a transfer to another room within the institution, if the purpose of the transfer is to relocate-- (i) A resident of a SNF, from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or	Guidelines: §483.10(o) This requirement applies to transfer within a physical plant. These provisions allow a resident to refuse transfer from a room in one distinct part of an institution to a room in another distinct part of the institution for purposes of obtaining Medicare or Medicaid eligibility. If a resident refuses to transfer from a portion of the institution that is not Medicare certified, the resident forgoes the possibility of Medicare coverage for the care received there. If that portion of the institution is Medicaid certified and the resident is Medicaid-eligible, then Medicaid covered services would be paid by Medicaid. If the resident is Medicaid-eligible, but that portion of the institution is not Medicaid certified, then the resident would assume responsibility for payment for the services. If the resident is unable to pay

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F177 Cont.	(ii) A resident of a NF, from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF. (2) A resident's exercise of the right to refuse transfer under paragraph (o)(1) of this section does not affect the individual's eligibility or entitlement to Medicare or Medicaid benefits.	for those services, then the facility may, after giving the resident a 30-day notice, transfer the resident under the provisions of §483.12(a). When a resident occupies a bed in a distinct part NF that participates in Medicaid and not in Medicare, he or she may not be moved involuntarily to another part of the institution by the facility (or required to be moved by the State) solely for the purpose of assuring Medicare eligibility for payment. Such moves are only appropriate when they occur at the request of a resident (for example, when a privately paying Medicare beneficiary believes that admission to a bed in a Medicare-participating distinct part of the institution may result in Medicare payment). See Guidelines: §483.12 for further discussion regarding transfers. For transfers of residents between Medicare or Medicaid approved distinct parts: o Is there a documented medical reason for the transfer? o Was the resident transferred because of a change in payment source? o If a Medicare or Medicaid resident is notified that he/she is no longer eligible, does the facility transfer the resident? Did the facility give the resident the opportunity to refuse the transfer? How? What happened? o Ask the local ombudsman about facility compliance with transfer requirements. See also §483.12 - Criteria for Transfer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§483.12 Admission, transfer and discharge rights.	Guidelines: §483.12 This requirement applies to transfers or discharges that are initiated by the facility, not by the resident. Whether or not a resident agrees to the facility's decision, these requirements apply whenever a facility initiates the transfer or discharge. "Transfer" is moving the resident from the facility to another legally responsible institutional setting, while "discharge" is moving the resident to a non-institutional setting when the releasing facility ceases to be responsible for the resident's care. If a resident is living in an institution participating in both Medicare and Medicaid (SNF/NF) under separate provider agreements, a move from either the SNF or NF would constitute a transfer. Transfer and discharge provisions significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility. The facility may not transfer or discharge the resident unless: 1. The transfer or discharge is necessary to meet the resident's welfare and the resident's welfare cannot be met in the facility; 2. The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; 3. The safety of individuals in the facility is endangered; 4. The health of individuals in the facility would otherwise be endangered; 5. The resident has failed, after reasonable and appropriate notice, to pay for a stay at the facility; or 6. The facility ceases to operate. To demonstrate that any of the events specified in 1 - 5 have occurred, the law requires documentation in the resident's clinical record. To demonstrate situations 1 and 2, the resident's physician must provide the documentation. In situation 4, the documentation must be provided by any physician. (See §483.12(a)(2).)
	(a) Transfer and discharge: (1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Moreover, before the transfer or discharge occurs, the law requires that the facility notify the resident and, if known, the family member, surrogate, or representative of the transfer and the reasons for the transfer, and record the reasons in the clinical record. The facility's notice must include an explanation of the right to appeal the transfer to the State as well as the name, address, and phone number of the State long-term care ombudsman. In the case of a developmentally disabled individual, the notice must include the name, address and phone number of the agency responsible for advocating for the developmentally disabled, and in the case of a mentally ill individual, the name, address and phone number of the agency responsible for advocating for mentally ill individuals. (See §483.12(a)(3) and (5).) Generally, this notice must be provided at least 30 days prior to the transfer. Exceptions to the 30-day requirement apply when the transfer is effected because of: o Endangerment to the health or safety of others in the facility; o When a resident's health has improved to allow a more immediate transfer or discharge; o When a resident's urgent medical needs require more immediate transfer; and o When a resident has not resided in the facility for 30 days. In these cases, the notice must be provided as soon as practicable before the discharge. (See §483.12(a)(4).) Finally, the facility is required to provide sufficient preparation and orientation to residents to ensure safe and orderly discharge from the facility. (See §483.12(a)(6).) Under Medicaid, a participating facility is also required to provide notice to its residents of the facility's bed-hold policies and readmission policies prior to transfer of a resident for hospitalization or therapeutic leave. Upon such transfer, the facility must provide written notice to the resident and an immediate family member, surrogate or representative of the duration of any bed-hold. With respect to readmission in a Medicaid participating facility, the facility must develop policies that permit residents eligible for Medicaid, who were transferred for hospitalization or therapeutic leave, and whose absence exceeds the bed-hold period as defined by the State plan, to return to the facility in the first available bed. (See §483.12(b).) A resident cannot be transferred for non-payment if he or she has submitted to a third party payor all the paperwork necessary for the bill to be paid. Non-payment would occur if a third party payor, including Medicare or Medicaid, denies the claim and the resident refused to pay for his or her stay. §483.10(o), F177 addresses the right of residents to refuse certain transfers within an institution on the basis of payment status.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F201	(2) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless-- (i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; (ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; (iii) The safety of individuals in the facility is endangered; (iv) The health of individuals in the facility would otherwise be endangered; (v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a nursing facility, the nursing facility may charge a resident only allowable charges under Medicaid; or	Guidelines: §483.12(a)(2) and (3) If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct the appropriate assessment to determine if a new care plan would allow the facility to meet the resident's needs. (See §483.20(b)(4)(iv), F274, for information concerning assessment upon significant change.) Conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment. Refusal of treatment would not constitute grounds for transfer, unless the facility is unable to meet the needs of the resident or protect the health and safety of others. Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy. Procedures: §483.12(a)(2) and (3) During closed record review, determine the reasons for transfer/discharge. o Do records document accurate assessments and attempts through care planning to address resident's needs through multi-disciplinary interventions, accommodation of individual needs and attention to the resident's customary routines? o Did the resident's physician document the record if: The resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization)? or The resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility. o Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered? o Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? Did the survey team observe residents with similar safety concerns in the facility? If so, determine differences between these residents and those who were transferred or discharged. o Look for changes in source of payment coinciding with transfer. If you find such transfer, determine if the transfers were triggered by one of the criteria specified in §483.12(a)(2). o Ask the ombudsman if there were any complaints regarding transfer and/or discharge. If there were, what was the result of the ombudsman's investigation? o If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F202	(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by-- (i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and (ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.	
F203	(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must-- (i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. (ii) Record the reasons in the resident's clinical record; and (iii) Include in the notice the items described in paragraph (a)(6) of this section.	Procedures: §483.12(a)(4)-(6) If the team determines that there are concerns about the facility's transfer and discharge actions, during closed record review, look at notices to determine if the notice requirements are met, including: o Advance notice (either 30 days or, as soon as practicable, depending on the reason for transfer/discharge); o Reason for transfer/discharge; o The effective date of the transfer or discharge; o The location to which the resident was transferred or discharged; o Right of appeal; o How to notify the ombudsman (name, address, and telephone number); and o How to notify the appropriate protection and advocacy agency for residents with mental illness or mental retardation (mailing address and telephone numbers). Determine whether the facility notified a family member or legal representative of the proposed transfer or discharge.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F203 Cont.	(5) Timing of the notice. (i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged. (ii) Notice may be made as soon as practicable before transfer or discharge when- (A) the safety of the individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section; (B) The health of individuals in the facility would be endangered, under (a)(2)(iv) of this section; (C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section; (D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or (E) A resident has not resided in the facility for 30 days. (6) Contents of the notice. The written notice specified in paragraph (a)(4) of this section must include the following:	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F203 Cont.	(i) The reason for transfer or discharge; (ii) The effective date of transfer or discharge; (iii) The location to which the resident is transferred or discharged; (iv) A statement that the resident has the right to appeal the action to the State; (v) The name, address and telephone number of the State long term care ombudsman; (vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and (vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F204	(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.	Guidelines: §483.12(a)(7) "Sufficient preparation" means the facility informs the resident where he or she is going and takes steps under its control to assure safe transportation. The facility should actively involve, to the extent possible, the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits, if possible, by the resident to a new location; working with family to ask their assistance in assuring the resident that valued possessions are not left behind or lost; orienting staff in the receiving facility to resident's daily patterns; and reviewing with staff routines for handling transfers and discharges in a manner that minimizes unnecessary and avoidable anxiety or depression and recognizes characteristic resident reactions identified by the resident assessment and care plan. Procedures: §483.12(a)(7) During Resident Review, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.
F205	(b) Notice of bed-hold policy and readmission -- (1) Notice before transfer. Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies--	Guidelines: §483.12(b)(1) and (2) The nursing facility's bed-hold policies apply to all residents. These sections require two notices related to the facility's bed-hold policies to be issued. The first notice of bed-hold policies could be given well in advance of any transfer. However, reissuance of the first notice would be required if the bed-hold policy under the State plan or the facility's policy were to change. The second notice, which specifies the duration of the bed-hold policy, must be issued at the time of transfer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F205 Cont.	(i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the nursing facility; and (ii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return. (2) Bed-hold notice upon transfer. At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.	In cases of emergency transfer, notice "at the time of transfer" means that the family, surrogate, or representative are provided with written notification within 24 hours of the transfer. The requirement is met if the resident's copy of the notice is sent with other papers accompanying the resident to the hospital. Bed-hold for days of absence in excess of the State's bed-hold limit are considered non-covered services which means that the resident could use his/her own income to pay for the bed-hold. However, if such a resident does not elect to pay to hold the bed, readmission rights to the next available bed are specified at §483.12(b)(3). Non-Medicaid residents may be requested to pay for all days of bed-hold. If residents (or their representatives in the case of residents who are unable to understand their rights) are unsure or unclear about their bed-hold rights, review facility bed-hold policies. o Do policies specify the duration of the bed-hold? o Is this time period consistent with that specified in the State plan? During closed record review, look at records of residents transferred to a hospital or on therapeutic leave to determine if bed-hold requirements were followed. Was notice given before and at the time of transfer? During closed record review, look at records of residents transferred to a hospital or on therapeutic leave to determine if bed-hold requirements were followed. Was notice given before and at the time of transfer?
F206	(3) Permitting resident to return to facility. A nursing facility must establish and follow a written policy under which a resident whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident--	Guidelines: §483.12(b)(3) "First available bed in a semi-private room" means a bed in a room shared with another resident of the same sex. (see §483.10(m) for the right of spouses to share a room.) Medicaid-eligible residents who are on therapeutic leave or are hospitalized beyond the State's bed-hold policy must be readmitted to the first available bed even if the residents have outstanding Medicaid balances. Once readmitted, however, these residents may be transferred if the facility can demonstrate that non-payment of charges exists and documentation and notice requirements are followed. The right to readmission is applicable to individuals seeking to return from a transfer or discharge as long as all of the specific qualifications set out in §483.12(b)(3) are met.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F206 Cont.	(i) Requires the services provided by the facility; and (ii) Is eligible for Medicaid nursing facility services.	Procedures: §483.12(b)(3) For Medicaid recipients whose hospitalization or therapeutic leave exceeds the bed-hold period, do facility policies specify readmission rights? Refer to the Minimum Data Set (MDS), Section A.10, Discharge Planned; MDS 2.0, section Q, Discharge Potential and Overall Status. Review the facility's written bed-hold policy to determine if it specifies legal readmission rights. Ask the local ombudsman if there are any problems with residents being readmitted to the facility following hospitalization. In closed record review, determine why the resident did not return to the facility. Ask the social worker or other appropriate staff what he/she tells Medicaid-eligible residents about the facility's bed-hold policies and the right to return and how Medicaid-eligible residents are assisted in returning to the facility. If potential problems are identified, talk to discharge planners at the hospital to which residents are transferred to determine their experience with residents returning to the facility.
F207	(c) Equal access to quality care. (1) A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all individuals regardless of source of payment; (2) The facility may charge any amount for services furnished to non-Medicaid residents consistent	Guidelines: §483.12(c) Facilities must treat all residents alike when making transfer and discharge decisions. "Identical policies and practices" concerning services means that facilities must not distinguish between residents based on their source of payment when providing services that are required to be provided under the law. All nursing services, specialized rehabilitative services, social services, dietary services, pharmaceutical services, or activities that are mandated by the law must be provided to residents according to residents' individual needs, as determined by assessments and care plans. Procedures: §483.12(c) Determine if residents are grouped in separate wings or floors for reasons other than care needs.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F207 Cont.	with the notice requirement in §483.10(b)(5)(i) and (b)(6) describing the charges; and (3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan. (d) Admissions policy.	
F208	(1) The facility must-- (i) not require residents or potential residents to waive their rights to Medicare or Medicaid; and (ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.	Guidelines: §483.12(d)(1) This provision prohibits both direct and indirect request for waiver of rights to Medicare or Medicaid. A direct request for waiver, for example, requires residents to sign admissions documents explicitly promising or agreeing not to apply for Medicare or Medicaid. An indirect request for waiver includes requiring the resident to pay private rates for a specified period of time, such as two years ("private pay duration of stay contract") before Medicaid will be accepted as a payment source for the resident. Facilities must not seek or receive any kind of assurances that residents are not eligible for, or will not apply for, Medicare or Medicaid benefits. Procedures: §483.12(d)(1) If concerns regarding admissions procedures arise during interviews, review admissions packages and contracts to determine if they contain prohibited requirements (e.g., "side agreements" for the resident to be private pay or to supplement the Medicaid rate). Ask staff what factors lead to decisions to place residents in different wings or floors. Note if factors other than medical and nursing needs affect these decisions. Do staff know the source of payment for the residents they take care of? Ask the ombudsman if the facility treats residents differently in transfer, discharge and covered services based on source of payment. With respect to transfer and discharge, if the facility appears to be sending residents to hospitals at the time (or shortly before) their payment source changes from private-pay or Medicare to Medicaid, call the hospitals and ask their discharge planners if they have detected any pattern of dumping. Also, ask discharge planners if the facility readmits Medicaid recipients who are ready to return to the facility. During the tour, observe possible differences in services.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F208 Cont.		o Observe if there are separate dining rooms. If so, are different foods served in these dining rooms? For what reasons? Are residents excluded from some dining rooms because of source of payment? o Observe the placement of residents in rooms in the facility. If residents are segregated on floors or wings by source of payment, determine if the facility is providing different services based on source of payment. Be particularly alert to differences in treatment and services. For example, determine whether less experienced aides and nursing staff are assigned to Medicaid portions of the facility. Notice the condition of the rooms (e.g., carpeted in private-pay wings, tile in Medicaid wings, proximity to the nurses' station, quality of food served as evening snacks). As part of closed record review, determine if residents have been treated differently in transfers or discharges because of payment status. For example, determine if the facility is sending residents to acute care hospitals shortly before they become eligible for Medicaid as a way of getting rid of Medicaid recipients. Ask social services staff to describe the facility's policy and practice on providing services, such as rehabilitative services. Determine if services are provided based on source of payment, rather than on need for services to attain or maintain functioning.
	(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.	Guidelines: §483.12(d)(2) The facility may not require a third person to accept personal responsibility for paying the facility bill out of his or her own funds. However, he or she may use the resident's money to pay for care. A third party guarantee is not the same as a third party payor, e.g., an insurance company; and this provision does not preclude the facility from obtaining information about Medicare or Medicaid eligibility or the availability of private insurance. The prohibition against third-party guarantees applies to all residents and prospective residents in all certified long term care facilities, regardless of payment source.
	(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,--	Guidelines: §483.12(d)(3) This requirement applies only to Medicaid certified nursing facilities. Facilities may not charge for any service that is included in the definition of "nursing facility services" and, therefore, required to be provided as part of the daily rate. Facilities may not accept additional payment from residents or their families as a prerequisite to admission or to continued stay in the facility. Additional payment includes deposits from Medicaid-eligible residents or their families, or any promise to pay private rates for a specified period of time.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F208 (Cont.)	(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and (ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident. (4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.	A nursing facility may charge a Medicaid beneficiary for a service the beneficiary has requested and received, only if: o That service is not defined in the State plan as a "nursing facility" service; o The facility informs the resident and the resident's representative in advance that this is not a covered service to allow them to make an informed choice regarding the fee; and o The resident's admission or continued stay is not conditioned on the resident's requesting and receiving that service. Procedures: §483.12(d)(3) Review State covered services. Compare with the list of items for which the facility charges to determine if the facility is charging for covered services. Determine if the facility requires deposits from residents. If you identify potential problems with discrimination, review the files of one or more residents selected for a focused or comprehensive review to determine if the facility requires residents to submit deposits as a precondition of admission besides what may be paid under the State plan. If interviews with residents suggest that the facility may have required deposits from Medicaid recipients at admission, except those admitted when Medicaid eligibility is pending, corroborate by, for example, reviewing the facility's admissions documents or interviewing family members.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221* F222**	§483.13 Resident Behavior and Facility Practices a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms. * Use tag #F221 for deficiencies concerning physical restraints. ** Use tag #F222 for deficiencies concerning chemical restraints	Intent: §483.13(a) The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints. Guidelines: §483.13(a) Definitions of Terms "Physical Restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body. "Chemical Restraints" is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms. "Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents. "Convenience" is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest. "Medical Symptom" is defined as an indication or characteristic of a physical or psychological condition. _____ Convenience is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest. Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident's unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The resident's right to participate in care planning and the right to refuse treatment are addressed at §§483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse restraints.

GUIDANCE TO SURVEYORS - LONG TERM CARE FACILITIES

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221 F222 (Cont.)		Physical Restraints are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body. "Physical restraints" include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily. Also included as restraints are facility practices that meet the definition of a restraint, such as: o Using side rails that keep a resident from voluntarily getting out of bed; o Tucking in or using velcro to hold a sheet, fabric, or clothing tightly so that a resident's movement is restricted; o Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident can not remove easily, that prevent the resident from rising; o Placing a resident in a chair that prevents a resident from rising; and o Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed. Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed. As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom. The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another. Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident. Medical Symptom is defined as an indication or characteristic of a physical or psychological condition. The resident's medical symptoms should not be viewed in isolation, rather the symptoms should be viewed in the context of the resident's condition, circumstances and environment. Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of the medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. Before a resident is restrained, the facility must determine the presence of a speciic medical symptom that would require the use of restraints, and how the use of

GUIDANCE TO SURVEYORS - LONG TERM CARE FACILITIES

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221 F222 (Cont.)		restraints would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being. Medical symptoms that warrant the use of restraints must be documented in the resident's medical record, ongoing assessments, and care plans. While there must be a physician's order reflecting the presence of a medical symptom, HCFA will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents whose care plans indicate the need for restraints, that the facility engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting. Consideration of Treatment Plan In order for the resident to be fully informed, the facility must explain, in the context of the individual resident's condition and circumstances, the potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use. Whenever restraint use is considered, the facility must explain to the resident how the use of restraints would treat the resident's medical symptoms and assist the resident in attaining or maintaining his/her highest practicable level of physical or psychological well-being. In addition, the facility must also explain the potential negative outcomes of restraint use which include, but are not limited to, declines in the resident's physical functioning (e.g., ability to ambulate) and muscle condition, contractures, increased incidence of infections and development of pressure sores/ulcers, delirium, agitation, and incontinence. Moreover, restraint use may constitute an accident hazard. Restraints have been found in some cases to increase the incidence of falls or head trauma due to falls and other accidents (e.g., strangulation, entrapment). Finally, residents who are restrained may face a loss of autonomy, dignity and self respect, and may show symptoms of withdrawal, depression, or reduced social contact. In effect, restraint use can reduce independence, functional capacity, and quality of life. Alternatives to restraint use should be considered and discussed with the resident. Alternatives to restraint use might include modifying the resident's environment and/or routine. In the case of a resident who is incapable of making a decision, the legal surrogate or representative may exercise this right based on the same information that would have been provided to the resident. (See §483.10(a)(3) and (4).) However, the legal surrogate or representative cannot give permission to use restraints for the sake of discipline or staff convenience or when the restraint is

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221 F222 (Cont.)		not necessary to treat the resident's medical symptoms. That is, the facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative's request or approval. Assessment and Care Planning for Restraint Use There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility's responsibility to assess and care plan restraint use on an ongoing basis. Before using a device for mobility or transfer, assessment should include a review of the resident's: o Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and o Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident's ability to transfer?). The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom. Interventions that the facility might incorporate in care planning include: o Providing restorative care to enhance abilities to stand, transfer, and walk safely; o Providing a device such as a trapeze to increase a resident's mobility in bed; o Placing the bed lower to the floor and surrounding the bed with a soft mat; o Equipping the resident with a device that monitors his/her attempts to arise; o Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom; o Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or o Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use. Procedures: §483.13(a) Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Since continued restraint use is associated with a potential for a decline in functioning if the risk is not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributed to a disease progression or inappropriate use of restraints.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221 F222 (Cont.)		For sampled residents observed as physically restrained during the survey or whose clinical records show the use of physical restraints within 30 days of the survey, determine whether the facility used the restraint for convenience or discipline, or a therapeutic intervention for specific periods to attain and maintain the resident's highest practicable physical, mental, or psychosocial well-being. Probes: §483.13(a) This systematic approach should answer these questions: 1. What are the medical symptoms that led to the consideration of the use of restraints? 2. Are these symptoms caused by failure to: a. Meet individual needs in accordance with the resident assessments including, but not limited to, section III of the MDS, Customary Daily Routines (MDS version 2.0 section AC), in the context of relevant information in sections I and II of the MDS (MDS version 2.0 sections AA and AB)? b. Use rehabilitative/restorative care? c. Provide meaningful activities? d. Manipulate the resident's environment, including seating? 3. Can the cause(s) of the medical symptoms be eliminated or reduced? 4. If the cause(s) cannot be eliminated or reduced, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use? (See Physical Restraints Resident Assessment Protocol (RAP), paragraph I). 5. If alternatives have been tried and deemed unsuccessful, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce the potential for negative outcomes while continually trying to find and use less restrictive alternatives? 6. Did the resident or legal surrogate make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained? 7. Does the facility use the Physical Restraints RAP to evaluate the appropriateness of restraint use? 8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained residents' strength and mobility?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F223	(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.	Intent: §483.13(b) Each resident has the right to be free from abuse, corporal punishment, and involuntary seclusion. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the resident, family members or legal guardians, friends, or other individuals. Guidelines: §483.13(b) and (c) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." (42 CFR 488.301) This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. "Verbal abuse" is defined as the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that he/she will never be able to see his/her family again. "Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault. "Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment. "Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F223 (Cont.)		Involuntary seclusion" is defined as separation of a resident from other residents or from her/his room or confinement to her/his room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other Residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs. Investigation of possible involuntary seclusion, may involve one of two types of situations: that in which residents are living in an area of the facility that restricts their freedom of movement throughout the facility, or that in which a resident is temporarily separated from other residents. o If the stated purpose of a unit which prevents residents from free movement throughout the facility is to provide specialized care for residents who are cognitively impaired, then placement in the unit is not considered involuntary seclusion, as long as care and services are provided in accordance with each resident's individual needs and preferences rather than for staff convenience, and as long as the resident, surrogate, or representative (if any) participates in the placement decision, and is involved in continuing care planning to assure placement continues to meet resident needs and preferences. o If a resident is receiving emergency short-term monitored separation due to temporary behavioral symptoms (such as brief catastrophic reactions or combative or aggressive behaviors which pose a threat to the resident, other residents, staff or others in the facility), this is not considered involuntary seclusion as long as this is the least restrictive approach for the minimum amount of time, and is being done according to resident needs and not for staff convenience. If a resident is being temporarily separated from other residents, i.e., for less than 24 hours, as an emergency short-term intervention, answer these questions: 1. What are the symptoms that led to the consideration of the separation? 2. Are these symptoms caused by failure to: a. Meet individual needs? b. Provide meaningful activities?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F223 (Cont.)		c. Manipulate the resident's environment? 3. Can the cause(s) be removed? 4. If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation? 5. If these alternatives have been tried and found ineffective, does the facility use separation for the least amount of time? 6. To what extent has the resident, surrogate or representative (if any) participated in care planning and made an informed choice about separation? 7. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives? If, during the course of the survey, you identify the possibility of abuse according to the definitions above, investigate through interviews, observations, and record review. (For investigative options, refer to the Guidelines for Complaint Investigation which outlines the steps of investigations for various types of suspected abuse and misappropriation of property.) Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse and where and when it occurred. Ensure that the facility addresses the incident immediately.
F224* F226**	(c) Staff treatment of residents. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. • Use tag F224 for deficiencies concerning mistreatment, neglect or misappropriation of resident property.	Intent: §483.13(c), F224 Each resident has the right to be free from mistreatment, neglect and misappropriation of property. This includes the facility's identification of residents whose personal histories render them at risk for abusing other residents, and development of intervention strategies to prevent occurrences, monitoring for changes that would trigger abusive behavior, and reassessment of the interventions on a regular basis. Intent: §483.13(c), F226 The facility must develop and operationalize policies and procedures for screening and training employees, protection of residents and for the prevention, identification, investigation, and reporting of abuse, neglect, mistreatment, and misappropriation of property. The purpose is to assure that the facility is doing all that is within its control to prevent occurrences.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F224* F226** (Cont.)	** Use tag F226 for deficiencies concerning the facility's development and implementation of policies and procedures	Guidelines:§483.13(c), F224 Neglect" means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (42 CFR 488.301) "Misappropriation of resident property" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent. (42 CFR 488.301) 483.13 (c), F226 The facility must develop and implement policies and procedures that include the seven components: screening, training, prevention, identification, investigation, protection and reporting/response. The items under each component listed below are examples of ways in which the facility could operationalize each component. **I. Screening (483.13(c)(1)(ii)(A)&(B):** Have procedures to: o Screen potential employees for a history of abuse, neglect or mistreating residents as defined by the applicable requirements at 483.13(c)(1)(ii)(A) and (B). This includes attempting to obtain information from previous employers and/or current employers, and checking with the appropriate licensing boards and registries. **II. Training (42 CFR 483.74(e)):** Have procedures to: o Train employees, through orientation and on-going sessions on issues related to abuse prohibition practices such as: - Appropriate interventions to deal with aggressive and/or catastrophic reactions of residents; - How staff should report their knowledge related to allegations without fear of reprisal; - How to recognize signs of burnout, frustration and stress that may lead to abuse; and - What constitutes abuse, neglect and misappropriation of resident property.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F224* F226** (Cont.)		**III. Prevention (483.13(b) and 483.13(c)):** Have procedures to: o Provide residents, families and staff information on how and to whom they may report concerns, incidents and grievances without the fear of retribution; and provide feedback regarding the concerns that have been expressed. (See 483.10(f) for further information regarding grievances.) o Identify, correct and intervene in situations in which abuse, neglect and/or misappropriation of resident property is more likely to occur. This includes an analysis of: - Features of the physical environment that may make abuse and/or neglect more likely to occur, such as secluded areas of the facility; - The deployment of staff on each shift in sufficient numbers to meet the needs of the residents, and assure that the staff assigned have knowledge of the individual residents' care needs; - The supervision of staff to identify inappropriate behaviors, such as using derogatory language, rough handling, ignoring residents while giving care, directing residents who need toileting assistance to urinate or defecate in their beds; and - The assessment, care planning, and monitoring of residents with needs and behaviors which might lead to conflict or neglect, such as residents with a history of aggressive behaviors, residents who have behaviors such as entering other residents' rooms, residents with self-injurious behaviors, residents with communication disorders, those that require heavy nursing care and/or are totally dependent on staff. **IV. Identification (483.13(c)(2)):** Have procedures to: o Identify events, such as suspicious bruising of residents, occurrences, patterns, and trends that may constitute abuse; and to determine the direction of the investigation. **V. Investigation (483.13(c)(3))**: Have procedures to: o Investigate different types of incidents; and o Identify the staff member responsible for the initial reporting, investigation of alleged violations and reporting of results to the proper authorities. (See 483.13 (c)(2), (3), and (4).)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F224* F226** (Cont.)		**VI. Protection (483.13(c)(3)**: Have procedures to: o Protect residents from harm during an investigation. **VII. Reporting/Response (483.13(c)(1)(iii), 483.13(c)(2) and 483.13(c)(4))**: Have procedures to: o Report all alleged violations and all substantiated incidents to the state agency and to all other agencies as required, and take all necessary corrective actions depending on the results of the investigation; o Report to the State nurse aide registry or licensing authorities any knowledge it has of any actions by a court of law which would indicate an employee is unfit for service; and o Analyze the occurrences to determine what changes are needed, if any, to policies and procedures to prevent further occurrences.
Refer to F223	(1) The facility must-- (i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;	
F225	(ii) Not employ individuals who have been-- (A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or (B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and (iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.	Intent: §483.13(c)(1)(ii) and (iii) The facility must not hire a potential employee with a history of abuse, if that information is known to the facility. The facility must report knowledge of actions by a court of law against an employee that indicates the employee is unfit for duty. The facility must report alleged violations, conduct an investigation of all alleged violations, report the results to proper authorities, and take necessary corrective actions. Facilities must be thorough in their investigations of the past histories of individuals they are considering hiring. In addition to inquiry of the State nurse aide registry or licensing authorities, the facility should check information from previous and/or current employers and make reasonable efforts to uncover information about any past criminal prosecutions. Guidelines: §483.13(c)(1)(ii) and (iii) "Found guilty. . .by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere. "Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents, or misappropriation of their property.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F225 (Cont.)	(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency). (3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress. (4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken	A certified nurse aide found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have her/his name entered into the nurse aide registry. A licensed staff member found guilty of the above must be reported to their licensing board. Further, if a facility determines that actions by a court of law against an employee are such that they indicate that the individual is unsuited to work in a nursing home (e.g., felony conviction of child abuse, sexual assault, or assault with a deadly weapon), then the facility must report that individual to the nurse aide registry (if a nurse aide) or to the State licensing authorities (if a licensed staff member). Such a determination by the facility is not limited to mistreatment, neglect and abuse of residents and misappropriation of their property, but to any treatment of residents or others inside or outside the facility which the facility determines to be such that the individual should not work in a nursing home environment. A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual. The facility's reporting requirements under 483.13(c)(2) and (4) include reporting both alleged violations and the results of investigations to the State survey agency.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F240	§483.15 Quality of life. A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.	Guidelines: §483.15 The intention of the quality of life requirements is to specify the facility's responsibilities toward creating and sustaining an environment that humanizes and individualizes each resident. Compliance decisions here are driven by the quality of life each resident experiences.
F241	(a) Dignity. The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.	Guidelines: §483.15(a) "Dignity" means that in their interactions with residents, staff carries out activities that assist the resident to maintain and enhance his/her self-esteem and self-worth. For example: o Grooming residents as they wish to be groomed (e.g., hair combed and styled, beards shaved/trimmed, nails clean and clipped); o Assisting residents to dress in their own clothes appropriate to the time of day and individual preferences; o Assisting residents to attend activities of their own choosing; o Labeling each resident's clothing in a way that respects his or her dignity; o Promoting resident independence and dignity in dining (such as avoidance of day-to-day use of plastic cutlery and paper/plastic dishware, bibs instead of napkins, dining room conducive to pleasant dining, aides not yelling); o Respecting resident's private space and property (e.g., not changing radio or television station without resident's permission, knocking on doors and requesting permission to enter, closing doors as requested by the resident, not moving or inspecting resident's personal possessions without permission); o Respecting resident's social status, speaking respectfully, listening carefully, treating residents with respect (e.g., addressing the resident with a name of the resident's choice, not excluding residents from conversations or discussing residents in community setting); and o Focusing on residents as individuals when they talk to them and addressing residents as individuals when providing care and services. Procedures: §483.15(a) For sampled residents, use the Resident Assessment Instrument (RAI) and comprehensive care plan to consider the resident's former life style and personal choices made while in the facility to obtain a picture of characteristic resident behaviors. As part of the team's information gathering and decision-making, look at the actions and omissions of staff and the uniqueness of the individual sampled resident and on the needs and preferences of the resident, not on the actions and omissions themselves.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F241 Cont.		Throughout the survey, observe: Do staff show respect for residents? When staff interact with a resident, do staff pay attention to the resident as an individual? Do staff respond in a timely manner to the resident's requests for assistance? In group activities, do staff focus attention on the group of residents? Or, do staff appear distracted when they interact with residents? For example, do staff continue to talk with each other while doing a "task" for a resident(s) as if she/he were not present? If the survey team identifies potential compliance issues regarding the privacy of residents during treatment, refer to §483.10(e) F164.
F242	(b) Self-determination and participation. The resident has the right to-- (1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care; (2) Interact with members of the community both inside and outside the facility; and (3) Make choices about aspects of his or her life in the facility that are significant to the resident.	Procedures: §483.15(b) Observe how well staff know each resident and what aspects of life are important to him/her. Determine if staff make adjustments to allow residents to exercise choice and self-determination. Review MDS Background Information III (MDS version 2.0 section AC) for customary routines. For sampled residents, review MDS to determine level of participation in assessment and care planning by resident and family members. Review MDS, Section G (MDS version 2.0 section F) for Psychosocial Well-Being and Care Planning. If the facility has failed to reasonably accommodate the preferences of the resident consistent with interests, assessments and plan of care, see F246, §483.15(e). Guidelines: §483.15(b)(3) The intent of this requirement is to specify that the facility must create an environment that is respectful of the right of each resident to exercise his or her autonomy regarding what the resident considers to be important facets of his or her life. For example, if a facility changes its policy and prohibits smoking, it must allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents. Weather permitting, this may be an outside area. Residents admitted after the facility changes its policy must be informed of this policy at admission. (See §483.10(b)(1)). Or, if a resident mentions that her therapy is scheduled at the time of her favorite television program, the facility should accommodate the resident to the extent that it can.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F243	(c) Participation in resident and family groups. (1) A resident has the right to organize and participate in resident groups in the facility; (2) A resident's family has the right to meet in the facility with the families of other residents in the facility; (3) The facility must provide a resident or family group, if one exists, with private space; (4) Staff or visitors may attend meetings at the group's invitation; (5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result form group meetings; F244 (6) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.	Guidelines: §483.15(c) This requirement does not require that residents' organize a residents or family group. However, whenever residents or their families wish to organize, facilities must allow them to do so without interference. The facility must provide the group with space, privacy for meetings, and staff support. Normally, the designated staff person responsible for assistance and liaison between the group and the facility's administration and any other staff members attend the meeting only if requested. "A resident's or family group" is defined as a group that meets regularly to: o Discuss and offer suggestions about facility policies and procedures affecting residents' care, treatment, and quality of life; o Support each other; o Plan resident and family activities; o Participate in educational activities; or o For any other purpose. The facility is required to listen to resident and family group recommendations and grievances. Acting upon these issues does not mean that the facility must accede to all group recommendations, but the facility must seriously consider the group's recommendations and must attempt to accommodate those recommendations, to the extent practicable, in developing and changing facility policies affecting resident care and life in the facility. The facility should communicate its decisions to the resident and/or family group. Procedures: §483.15(c) If no organized group exists, determine if residents have attempted to form one and have been unsuccessful, and, if so, why.
F245	(d) Participation in other activities. A resident has the right to participate in social, religious, and community activities that do	Guidelines: §483.15(d) The facility, to the extent possible, should accommodate an individual's needs and choices for how he/she spends time, both inside and outside the facility. Ask the social worker or other appropriate staff how they help residents pursue activities outside the facility.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F245 Cont.	not interfere with the rights of other residents in the facility.	Guidelines: §483.15(e) "Reasonable accomodations of individual needs and preferences," is defined as the facility's efforts to individualize the resident's environment. The facility's physical environmnet and staff behaviors should be directed toward assisting the resident in maintaining and/or achieving independent functioning, dignity, and well-being to the extent possible in accordance with the resident's own preferences, assesment and care plans. The facility should attempt to adapt such things as schedules, call systems, and room arrangements to accommodate residents' preferences, desires, and unique needs. This requirement applies to areas and environment in accordance with needs and preferences NOT addresses at: §§483.10(k), Telephone; 483.10(1), Personal property; 483.10(m), Married couples; 483.15(b), Self-Determination and participation; 483.15(f)(1), Activities; 483.15(g)(1), Social Services; 483-15(h)(1), Homelike environment; 483.25(a)(2) and (3), Treatment and services , Activities of daily living;483.25(f)(1), Psychosocial functioning; 483.25(h)(2), Accidents, Prevention-assistive devices; 483.35(d)(3), Food prepared in a form designed to meet individual needs. The facility must demonstrate that it accommodates residents' needs. For example, if the resident refuses a bath because he or she prefers a shower, prefers it at a different time of day or on a different day, does not feel well that day, is uneasy about the aide assigned to help or is worried about falling, the staff should make the necessary adjustments realizing the resident is not refusing to be clean but refusing the bath under the circumstance provided. The facility staff should meet with the resident to make adjustments in the care plan to accommodate his or her needs. This includes learning the residents preferences and taking them into account when discussing changes of rooms or roommates and the timing of such changes. In addition, this also includes making necessary adjustments to ensure that residents are able to reach call cords, buttons or other communication mechanisms, as well as accommodating food activities or room choices. Procedures: §483.15(e) Observe resident-staff interaction and determine to what extent staff attempt to accommodate residents' preferences. For those areas not addressed in other regulations, determine what happens when a resident states a preference in the form of a refusal. How does the staff attempt to learn what the resident is refusing, and why, and make adjustments to an extent practicable to meet the resident's needs?
	(e) Accommodation of needs. A resident has the right to--	
F246	(1) Reside and receive services in the facility with reasonable accommodations of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and	
F247	(2) Receive notice before the resident's room or roommate in the facility is changed.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F247 Cont.		Probes: §483.15(e) o Are rooms arranged such that residents in wheel chairs can easily access personal items and nsfer in and out of bed? o Does the facility respond to residents' stated needs and preferences? o If the resident is unable to express needs and preferences that would individualize care, has the family expressed the resident's routine and has the facility responded? Guidelines: §483.15(e)(1) Review the extent to which the facility adapts the physical environment to enable residents to maintain unassisted functioning. These adaptations include, but are not limited to: 1. Furniture and adaptive equipment that enable residents to: a. Stand independently; b. Transfer without assistance (e.g., arm supports, correct chair height, firm support); c. Maintain body symmetry; and d. Participate in resident-preferred activities. 2. Measures that: a. Enable residents with dementia to walk freely; b. Reorient and remotivate residents with restorative potential (e.g., displaying easily readable calendars and clocks, wall hangings evocative of the lives of residents); c. Promote conversation and socialization (pictures and decorations that speak to the resident's age cohort); and d. Promote mobility and independence for disabled residents in going to the bathroom (e.g., grab bars, elevated toilet seats). Determine if staff use appropriate measures to facilitate communication with residents who have difficulty communicating. For example, if necessary, does staff get at eye level, allow t remove a resident from noisy surroundings? Determine if staff communicate effectively with residents with cognitive impairments, such as referring in a non-contradictory way to what residents are saying, and addressing what residents are trying to express to the agenda behind their behavior. Probes: §483.15(e)(1)(2) How have residents' needs been accommodated? Do environmental adaptions enhance residents' independence, self-control, and highest practicable well-being? Is the fit between residents' needs and environment positive?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F248	(f) Activities. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.	Guidelines: §483.15(f)(1) Because the activities program should occur within the context of each resident's comprehensive assessment and care plan, it should be multi-faceted and reflect each individual resident's needs. Therefore, the activities program should provide stimulation or solace; promote physical, cognitive and/or emotional health; enhance, to the extent practicable, each resident's physical and mental status; and promote each resident's self-respect by providing, for example, activities that support self-expression and choice. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers and visitors. Probes: §483.15(f)(1) Observe individual, group and bedside activities. 1. Are residents who are confined or choose to remain in their rooms provided with in room activities in keeping with life-long interests (e.g., music, reading, visits with individuals who share their interests or reasonable attempts to connect the resident with such individuals) and in-room projects they can work on independently? Do any facility staff members assist the resident with activities he or she can pursue independently? 2. If residents sit for long periods of time with no apparently meaningful activities, is the cause: a. Resident choice; b. Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities; c. Lack of assistance with ambulation; d. Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs. e. Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex? For residents selected for a comprehensive review, or a focused review, as appropriate, determine to what extent the activities reflect the individual resident's assessment. (See especially MDS III.1 and Sections B, C. D, and I.; MDS version 2.0 sections AC, B, C, D and N.) Review the activity calendar for the month prior to the survey to determine if the formal activity program:

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F248 Cont.	(2) The activities program must be directed by a qualified professional who-- (i) Is a qualified therapeutic recreation specialist or an activities professional who-- (A) Is licensed or registered, if applicable, by the State in which practicing; and (B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or	o Reflects the schedules, choices and rights of the residents; o Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends); o Reflects the cultural and religious interests of the resident population; and o Would appeal to both men and women and all age groups living in the facility. Review clinical records and activity attendance records of residents receiving a comprehensive review, or a focused review, as appropriate, to determine if: o Activities reflect individual resident history indicated by the comprehensive assessment; o Care plans address activities that are appropriate for each resident based on the comprehensive assessment; o Activities occur as planned; and o Outcomes/responses to activities interventions are identified in the progress notes of each resident. Guidelines: §483.15(f)(2) A "recognized accrediting body" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists. Procedures: §483.15(f)(2) If there are problems with provision of activities, determine if these services are provided by qualified staff.
F249	(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or (iii) Is a qualified occupational therapist or occupational therapy assistant; or (iv) Has completed a training course approved by the State.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(g) Social Services.	Intent: §483.15(g) To assure that sufficient and appropriate social services are provided to meet the resident's needs Guidelines: §483.15(g)(1) Regardless of size, all facilities are required to provide for the medically related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. It is not required that a qualified social worker necessarily provide all of these services. Rather, it is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate disciplines. "Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services might include, for example: o Making arrangements for obtaining needed adaptive equipment, clothing, and personal items; o Maintaining contact with facility (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning; o Assisting staff to inform residents and those they designate about the resident's health status and health care choices and their ramifications; o Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation); o Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements); o Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities); o Providing or arranging provision of needed counseling services; o Through the assessment and care planning process, identifying and seeking ways to support residents' individual needs; o Promoting actions by staff that maintain or enhance each resident's dignity in full recognition of each resident's individuality; o Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;
F250	1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F250 Cont.		o Finding options that most meet the physical and emotional needs of each resident; o Providing alternatives to drug therapy or restraints by understanding and communicating to staff why residents act as they do, what they are attempting to communicate, and what needs the staff must meet; o Meeting the needs of residents who are grieving; and o Finding options which most meet their physical and emotional needs Factors with a potentially negative effect on physical, mental, and psychosocial well being include an unmet need for: o Dental /denture care; o Podiatric care; o Eye Care; o Hearing services o Equipment for mobility or assistive eating devices; and o Need for home-like environment, control, dignity, privacy Where needed services are not covered by the Medicaid State plan, nursing facilities are still required to attempt to obtain these services. For example, if a resident requires transportation services that are not covered under a Medicaid state plan, the facility is required to arrange these services. This could be achieved, for example, through obtaining volunteer assistance. Types of conditions to which the facility should respond with social services by staff or referral include: o Lack of an effective family/support system; o Behavioral symptoms; o If a resident with dementia strikes out at another resident, the facility should evaluate the resident's behavior. For example, a resident may be re-enacting an activity he or she used to perform at the same time everyday. If that resident senses that another is in the way of his re-enactment, the resident may strike out at the resident impeding his or her progress. The facility is responsible for the safety of any potential resident victims while it assesses the circumstances of the residents behavior); o Presence of a chronic disabling medical or psychological condition (e.g., multiple sclerosis, chronic obstructive pulmonary disease, Alzheimer's disease, schizophrenia); o Depression o Chronic or acute pain; o Difficulty with personal interaction and socialization skills; o Presence of legal or financial problems o Abuse of alcohol or other drugs; o Inability to cope with loss of function; o Need for emotional support;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F250 Cont.		o Changes in family relationships, living arrangements, and/or resident's condition or functioning; and o A physical or chemical restraint. For residents with or who develop mental disorders as defined by the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), see §483.45, F406. Probes: §483.15(g)(1) For residents selected for a comprehensive or focused review as appropriate: o How do facility staff implement social services interventions to assist the resident in meeting treatment goals? o How do staff responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly? o How does the care plan link goals to psychosocial functioning/well-being? o Have the staff responsible for social work established and maintained relationships with the resident's family or legal representative? o [NFs] What attempts does the facility make to access services for Medicaid recipients when those services are not covered by a Medicaid State Plan? Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality. For sampled residents, review MDS, Section H.
F251	(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis. (3) Qualifications of a social worker. A qualified social worker is an individual with-- (i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and	Procedures: §483.15(g)(2) and (3) If there are problems with the provision of social services in a facility with over 120 beds, determine if a qualified social worker is employed on a full time basis. See also F250.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F251 Cont.	(ii) One year of supervised social work experience in a health care setting working directly with individuals.	
F252	(h) Environment. The facility must provide-- (1) A safe, clean, comfortable and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;	Guidelines: §483.15(h)(1) For "safe" environment, also see Guidelines for §§483.25(h), Accidents, and 483.70(a), Life Safety Code. For personal belongings, also see §§483.10(l), Personal property. For "comfortable" environment, see Guidelines for 483.15(h)(5), Adequate and comfortable lighting levels; 483.15(h)(6), Comfortable and safe temperature levels; and 483.15(h)(7), Comfortable sound levels. A determination of "comfortable and homelike" should include, whenever possible, the resident's or representative of the resident's opinion of the living environment. The absence of a personalized, homelike environment in a resident's room, is not meaningful unless the survey team determines that the absence of personal belongings is a result of facility practices, rather than the result of resident choice or circumstances (e.g., lack of resident funds, lack of family support system, resident's reason for being in the facility, such as short-term rehabilitation). A "homelike environment" is one that de-emphasizes the institutional character of the setting, to the extent possible, and allows the resident to use those personal belongings that support a homelike environment. A personalized, homelike environment recognizes the individuality and autonomy of the resident, provides an opportunity for self-expression and encourages links with the past and family members. Use this Tag when the facility fails to allow the resident to personalize his or her individual environment to the extent possible. Use Tag F224 (483.15(c)) if the facility fails to have a system in place to prevent the misappropriation of resident's property. See §483.10(l) for the requirement regarding personal property. For purposes of this requirement, "environment" refers to any environment in the facility that is frequented by residents, including the residents' rooms, bathrooms, hallways, activity areas, and therapy areas. If the survey team observes that the rooms of residents with dementia do not appear to be homelike, determine if this decision was made in the context of assessment and care planning; i.e., that this environment assists these residents to maintain their highest practicable functioning levels.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F252 Cont.		If the team observes non-homelike environments for residents with dementia, determine if each of these residents have the same plan of care and the reason why each of these residents have the same plan of care. By observing the residents' surroundings, what can the survey team learn about their everyday life and interests? Their life prior to residing in the facility? Observe for family photographs, books and magazines, bedspreads, knickknacks, mementos, and furniture that belong to the residents. For residents who have no relatives or friends, and have few assets, determine the extent to which the facility has assisted these residents to make their rooms homelike, if they so desire.
F253	(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;	Intent: §483.15(h)(2) The intent of this requirement is to focus on the facility's responsibility to provide effective housekeeping and maintenance services. Guidelines: §483.15(h)(2) "Sanitary" includes, but is not limited to, preventing the spread of disease-causing organisms by keeping resident care equipment clean and properly stored. Resident care equipment includes toothbrushes, dentures, denture cups, glasses and water pitchers, emesis basins, hair brushes and combs, bed pans, urinals, feeding tubes, leg bags and catheter bags, pads and positioning devices. For kitchen sanitation, see §483.70(h), Physical Environment, other environmental conditions. For facility-wide sanitary practices affecting the quality of care, see §483.65, Infection Control. "Orderly" is defined as an uncluttered physical environment that is neat and well-kept. Procedures: §483.15(h)(2) Balance the resident's need for a homelike environment and the requirements of having a "sanitary" environment in a congregate living situation. For example, a resident may prefer a cluttered room, but does this clutter result in unsanitary or unsafe conditions? Probes: §483.15(h)(2) Is resident care equipment sanitary? Is the area orderly? Is the area uncluttered and in good repair? Can residents and staff function unimpeded?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F254	(3) Clean bed and bath linens that are in good condition;	Probes: §483.15(h)(3) Are bed linens clean and in good condition? Are there clean towels and wash cloths in good condition available for the resident? Guidelines: §483.15(h)(4) §483.70(d)(2)(iv) states: "The facility must provide each resident with individual closet space in his/her bedroom with clothes racks and shelves accessible to the resident." Probes: §483.15(h)(4) Are there individual closet spaces with accessible shelves? Also see F470.
F255	(4) Private closet space in each resident room, as specified in §483.70(d)(2)(iv) of this part;	
F256	(5) Adequate and comfortable lighting levels in all areas;	Guidelines: §483.15(h)(5) "Adequate lighting" is defined as levels of illumination suitable to tasks the resident chooses to perform or the facility staff must perform. For some residents (e.g., those with glaucoma), lower levels of lighting would be more suitable. "Comfortable" lighting is defined as lighting which minimizes glare and provides maximum resident control, where feasible, over the intensity, location, and direction of illumination so that visually impaired residents can maintain or enhance independent functioning. Procedures: §483.15(h)(5) Are there adequate and comfortable lighting levels for individual resident and staff work needs? Consider the illumination available from any source, natural or artificial. For hallways, observe the illumination that is normally present. For resident rooms or for other spaces where residents can control the lighting, turn on the lights and make the rating under these conditions.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F257	(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71-81° F; and	Procedures: §483.15(h)(6) "Comfortable and safe temperature levels" means that the ambient temperature should be in a relatively narrow range that minimizes residents' susceptibility to loss of body heat and risk of hypothermia or susceptibility to respiratory ailments and colds. Although there are no explicit temperatures standards for facilities certified on or before October 1, 1990, these facilities still must maintain safe and comfortable temperature levels. For facilities certified after October 1, 1990, temperatures may exceed the upper range of 81° Fahrenheit for facilities in geographic areas of the country (primarily at the northernmost latitudes) where that temperature is exceeded only during rare, brief unseasonably hot weather. This interpretation would apply in cases where it does not adversely affect resident health and safety, and would enable facilities in areas of the country with relatively cold climates to avoid the expense of installing air conditioning equipment that would only be needed infrequently. Conversely, the temperatures may fall below 71° Fahrenheit for facilities in areas of the country where that temperature is exceeded only during brief episodes of unseasonably cold weather (minimum temperature must still be maintained at a sufficient level to minimize risk of hypothermia and susceptibility to loss of body heat, respiratory ailments and colds.) Measure the air temperature above floor level in resident rooms, dining areas, and common areas. If the temperature is out of the 71-81 degree range, then ask staff what actions they take when residents complain of heat or cold, e.g., provide extra fluids during heat waves and extra blankets and sweaters in cold.
F258	7) For the maintenance of comfortable sound levels.	Guidelines: §483.15(h)(7) "Comfortable" sound levels do not interfere with resident's hearing and enhance privacy when privacy is desired, and encourage interaction when social participation is desired. Of particular concern to comfortable sound levels is the resident's control over unwanted noise. Procedures: §483.15(h)(7) Determine if the sound levels are comfortable to residents. Do residents and staff have to raise their voices to communicate over background sounds? Are sound levels suitable for the activities occurring in that space during observation? Consider whether residents have difficulty hearing or making themselves heard because of background sounds (e.g., overuse or excessive volume of intercom, shouting, loud TV,

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F258 Cont.		cleaning equipment). Consider if it is difficult for residents to concentrate because of distractions or background noises such as traffic, music, equipment, or staff behavior. Consider the comfort of sound levels based on the needs of the residents participating in a particular activity, e.g., the sound levels may have to be turned up for hard of hearing individuals watching TV or listening to the radio. Consider the effect of noise on the comfort of residents with dementia. o During resident reviews, ask residents if during evenings and at nighttime, sounds are at comfortable levels? (If yes) Have you told staff about it and how have they responded?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Refer to F272	§483.20: Resident Assessment. The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident's functional capacity.	§483.20 Intent: To provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, family members, or outside consultants and review of the resident's record.
F271	(a) Admission Orders. At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.	§483.20(a) Intent: To ensure the resident receives necessary care and services. §483.20(a) Guidelines: "Physician orders for immediate care" are those written orders facility staff need to provide essential care to the resident, consistent with the resident's mental and physical status upon admission. These orders should, at a minimum, include dietary, drugs (if necessary) and routine care to maintain or improve the resident's functional abilities until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F272	(b) Comprehensive assessments. (1) Resident Assessment Instrument. A facility must make a comprehensive assessment of a resident's needs, using the RAI specified by the State. The assessment must include at least the following: (i) Identification and demographic information (ii) Customary routine.	§483.20(b) Intent: To ensure that the RAI is used in conducting comprehensive assessments as part of an ongoing process through which the facility identifies the resident's functional capacity and health status. §483.20(b) Guidelines: The information required in §483.20(b)(i-xvi) is incorporated into the MDS, which forms the core of each State's approved RAI. Additional assessment information is also gathered using triggered RAPs. Each facility must use its State-specified RAI (which includes both the MDS and utilization guidelines which include the RAPs) to assess newly admitted residents, conduct an annual reassessment and assess those residents who experience a significant change in status. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or RAPs. The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident. Furthermore, the facility is responsible for addressing the resident's needs from the moment of admission. "Identification and demographic information" corresponds to MDS v 2.0 Sections AA, BB and A, and refers to information that uniquely identifies each resident and the facility in which he/she resides, date of entry into the facility and residential history. "Customary routine" corresponds to MDS v 2.0 Section AC, and refers to information regarding the resident's usual community lifestyle and daily routine in the year prior to the date of entry to the nursing home.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F272	(iii) Cognitive patterns. (iv) Communication. (v) Vision. (vi) Mood and behavior patterns. (vii) Psychosocial well-being (viii) Physical functioning and structural problems. (ix) Continence. (x) Disease diagnosis and health conditions.	"Cognitive patterns" (iii) corresponds to MDS v. 2.0 Section B. "Cognitive patterns" is defined as the resident's ability to problem solve, decide, remember, and be aware of and respond to safety hazards. "Communication" (iv) corresponds to MDS v. 2.0 Section C, and refers to the resident's ability to hear, understand others, make him or herself understood (with assistive devices if they are used). "Vision" (v) corresponds to MDS v. 2.0 Section D, and I.1.jj, kk, ll and mm, and refers to the resident's visual acuity, limitations and difficulties, and appliances used to enhance vision. "Mood and behavior patterns" (vi) corresponds to MDS v. 2.0 Section E, and refers to the resident's patterns of mood and behavioral symptoms. "Psychosocial well-being" (vii) corresponds to MDS v. 2.0 Sections E1o and p, and F and refers to the resident's positive or negative feelings about him or herself or his/her social relationships. "Physical functioning and structural problems" (viii) corresponds to MDS v. 2.0 Section G, and refers to the resident's physical functional status, ability to perform activities of daily living, and the resident's need for staff assistance and assistive devices or equipment to maintain or improve functional abilities. "Continence" (ix) corresponds to MDS v. 2.0, Section H, and refers to the resident's patterns of bladder and bowel continence (control), pattern of elimination, and appliances used. "Disease diagnoses and health conditions" (x) corresponds to MDS v. 2.0, Sections AB.9 and 10, I.1 and 2, and J.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(xi) Dental and nutritional status.	"Dental and nutritional status" (xi) corresponds to MDS v. 2.0, Sections K1 and L. "Dental condition status" refers to the condition of the teeth, gums, and other structures of the oral cavity that may affect a resident's nutritional status, communication abilities, or quality of life. The assessment should include the need for, and use of, dentures oar other dental appliances. "Nutritional status" corresponds to MDS v. 2.0, Section K2-6. Nutritional status refers to weight, height, hematologic and biochemical assessments, clinical observations of nutrition, nutritional intake, resident's eating habits and preferences, dietary restrictions, supplements, and use of appliances.
	(xii) Skin conditions.	"Skin conditions" (xii) corresponds to MDS v. 2.0 Sections M, G1a, G6a, H1a, H1b, and P4c, and refers to the resident's development, or risk of development of a pressure sore.
	(xiii) Activity pursuit.	"Activity pursuit" (xiii) corresponds to MDS v. 2.0 Sections N and AC. "Activity pursuit" refers to the resident's ability and desire to take part in activities which maintain or improve, physical, mental, and psychosocial well-being. Activity pursuits refer to any activity outside of activities of daily living (ADLs) which a person pursues in order to obtain a sense of well-being. Also, includes activities which provide benefits in self-esteem, pleasure, comfort, health education, creativity, success, and financial or emotional independence. The assessment should consider the resident's normal everyday routines and lifetime preferences.
	(xiv) Medications.	"Medications" (xiv) corresponds to MDS v. 2.0, Section O, and Section U, if completed. "Medications" refers to all prescription and over-the-counter medications taken by the resident, including dosage, frequency of administration, and recognition of significant side effects that would be most likely to occur in the resident. This information need not appear in the assessment. However, it must be in the resident's clinical record and included in the care plan.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(xv) Special treatments and procedures.	"Special treatments and procedures" (xv) corresponds to MDS v. 2.0 Sections K5, M5, and P1, and Section T, if completed. "Special treatments and procedures" refers to treatments and procedures that are not part of basic services provided. For example, treatment for pressure sores, nasogastric feedings, specialized rehabilitation services, respiratory care, or devices and restraints.
	(xvi) Discharge potential.	"Discharge potential" (xvi) corresponds to MDS v. 2.0 Section Q. "Discharge potential" refers to the facility's expectation of discharging the resident from the facility within the next 3 months.
	(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.	"Documentation of summary information (xvii) regarding the additional assessment performed through the resident assessment protocols (RAPs)" corresponds to MDS v. 2.0 Section V, and refers to documentation concerning which RAPs have been triggered, documentation of assessment information in support of clinical decision making relevant to the RAP, documentation regarding where, in the clinical record, information related to the RAP can be found, and for each triggered RAP, whether the identified problem was included in the care plan.
	(xviii) Documentation of participation in assessment.	"Documentation of participation in the assessment" corresponds to MDS v. 2.0 Section R, and refers to documentation of who participated in the assessment process. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.
F273	(2) *when required*. A facility must conduct a comprehensive assessment of a resident as follows: (i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)	§483.20(b)(2) Intent: To assess residents in a timely manner.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F274	(ii) Within 14 days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purpose of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)	§483.20(b)(2)(ii) Guidelines: The following are the criteria for significant changes: A significant change reassessment is generally indicated if decline or improvement is consistently noted in 2 or more areas of decline or 2 or more areas of improvement: Decline: o Any decline in activities of daily living (ADL) physical functioning where a resident is newly coded as 3, 4 or 8 Extensive Assistance, Total Dependency, activity did not occur (note that even if coding in both columns A and B of an ADL category changes, this is considered 1 ADL change); o Increase in the number of areas where Behavioral Symptoms are coded as "not easily altered" (e.g., an increase in the use of code 1's for E4B); o Resident's decision-making changes from 0 or 1, to 2 or 3; o Resident's incontinence pattern changes from 0 or 1 to 2, 3 or 4, or placement of an indwelling catheter; o Emergence of sad or anxious mood as a problem that is not easily altered; o Emergence of an unplanned weight loss problem (5% change in 30 days or 10% change in 180 days); o Begin to use trunk restraint or a chair that prevents rising for a resident when it was not used before; o Emergence of a condition/disease in which a resident is judged to be unstable;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F274 (Cont.)		o Emergence of a pressure ulcer at Stage II or higher, when no ulcers were previously present at Stage II or higher; or o Overall deterioration of resident's condition; resident receives more support (e.g., in ADLs or decision making). Improvement: o Any improvement in ADL physical functioning where a resident is newly coded as 0, 1, or 2 when previously scored as a 3, 4, or 8; o Decrease in the number of areas where Behavioral Symptoms or Sad or Anxious Mood are coded as "not easily altered;" o Resident's decision making changes from 2 or 3, to 0 or 1; o Resident's incontinence pattern changes from 2, 3, or 4 to 0 or 1; or o Overall improvement of resident's condition; resident receives fewer supports. If the resident experiences a significant change in status, the next annual assessment is not due until 366 days after the significant change reassessment has been completed.
F275	(iii) Not less than once every 12 months.	§483.20(b)(2)(iii) Guidelines: The annual resident assessment must be completed within 366 days after final completion of the most recent comprehensive resident assessment. §483.20(b)(2) Probes: o Has each resident in the sample been comprehensively assessed using the State-specified RAI within the regulatory timeframes (i.e., within 14 days after admission, on significant change in status, and at least annually)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F275 (Cont.)		o Has the facility identified, in a timely manner, those residents who have experienced a change? o Has the facility reassessed residents using the State-specific RAI who had a significant change in status within 14 days after determining the change was significant. o Has the facility gathered supplemental assessment information based on triggered RAPs prior to establishing the care plan? o Does information in the RAI correspond with information obtained during observations of and interviews with the resident, facility staff and resident's family?
F276	(c) *Quarterly review assessment*. A facility must assess a resident using the quarterly review instrument specified by the State and approved by HCFA not less frequently than once every 3 months.	§483.20(c) Intent: To assure that the resident's assessment is updated on at least a quarterly basis. §483.20(c) Guidelines: At least each quarter, the facility shall review each resident with respect to those MDS items specified under the State's quarterly review requirement. At a minimum, this would include all items contained in HCFA's standard quarterly review form. A Quarterly review assessment must be completed within 92 days of the date at MDS Item R2b of the most recent, clinical assessment (AA8a=1,2,3,4,5 or 10). If the resident has experienced a significant change in status, the next quarterly review is due no later than 3 months after the significant change reassessment. §483.20(c) Probes: o Is the facility assessing and acting, no less than once every 3 months, on the results of resident's functional and cognitive status examinations? o Is the quarterly review of the resident's condition consistent with information in the progress notes, the plan of care and your resident observations and interviews?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F286	(d) *Use*. A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record.	§483.20(d) Intent: Facilities are required to maintain 15 months of assessment data in the resident's active clinical record. §483.20(d) Guidelines: The requirement to maintain 15 months of data in the resident's active clinical record applies regardless of form of storage to all MDS forms, RAP Summary forms, Quarterly Assessment forms, Face Sheet Information and Discharge and Reentry Tracking Forms and MDS Correction Request Forms (including signed attestation). MDS assessments must be kept in the resident's active clinical record for 15 months following the final completion date, tracking forms for discharge and reentry must be kept for 15 months following the date of the event, Correction Request Forms must be kept for 15 months following the final completion date of the MDS Correction Request form. The information must be kept in a centralized location, accessible to all professional staff members (including consultants) who need to review the information in order to provide care to the resident. After the 15-month period, RAI information may be thinned from the clinical record and stored in the medical records department, provided that it is easily retrievable if requested by clinical staff, the State agency, or HCFA. Whether or not the facility's clinical record system is entirely electronic, a hard copy of all MDS forms, including the signatures of the facility staff attesting to the accuracy and completion of the records, must be maintained in the resident's clinical record.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Refer to F279	And use the results of the assessment to develop, review and revise the resident's comprehensive plan of care.	For guidance regarding the use of the results of the assessment (other than storage), see guidance at F279.
Refer to F285	(e) *Coordination*. A facility must coordinate assessments with the pre-admission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.	§483.20(e) Guidelines: With respect to the responsibilities under the Pre-Admission Screening and Resident Review (PASRR) program, the State is responsible for conducting the screens, preparing the PASRR report, and providing or arranging the specialized services that are needed as a result of conducting the screens. The State is required to provide a copy of the PASRR report to the facility. This report must list the specialized services that the individual requires and that are the responsibility of the State to provide. All other needed services are the responsibility of the facility to provide.
F287	(f) *Automated data processing requirement*. (1) *Encoding Data*. Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility: (i) Admission assessment. (ii) Annual assessment updates. (iii)Significant change in status assessments.	§483.20(f)(1-4) Intent: The intent is to enable a facility to better monitor a resident's decline and progress over time. Computer-aided data analysis facilitates a more efficient, comprehensive and sophisticated review of health data. The primary purpose of maintaining the assessment data is so a facility can monitor resident progress over time. The information should be readily available at all times. §483.20(f)(1-4) Guidelines: "Encoding" means entering MDS information into a computer. "Transmitting data" refers to electronically sending encoded MDS information, from the facility to the State database, using a modem and communications software.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F287 (Cont.)	(iv) Quarterly review assessments. (v) A subset of items upon a resident's transfer, reentry, discharge, and death. (vi) Background (face-sheet) information, if there is no admission assessment. (2) *Transmitting data*. Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the State information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by HCFA and the State. (3) *Monthly transmittal requirements*. A facility must electronically transmit, at least monthly, encoded, accurate, complete MDS data to the State for all assessments conducted during the previous month, including the following:	"Capable of transmitting" means that the facility has encoded and edited according to HCFA specifications, the record accurately reflects the resident's overall clinical status as of the assessment reference date, and the record is ready for transmission. "Passing standard edits" means that the encoded responses to MDS items are consistent and within range, in accordance with HCFA specified standards. In general, inconsistent responses are either not plausible or ignore a skip pattern on the MDS. An example of inconsistency would be if one or more MDS items on a list were checked as present, and the "None of the Above" response was also checked for the same list. Out of range responses are invalid responses, such as using a response code of 2 for an MDS item for which the valid responses are zero or 1. "Monthly Transmittal" means electronically transmitting to the State, an MDS record that passes HCFA's standard edits, within 31 days of the final completion date of the record. "Accurate" means that the encoded MDS data matches the MDS form in the clinical record. Also refer to guidance regarding accuracy at §483.20(g), and the information accurately reflects the resident's status as of the Assessment Reference Date at MDS Item A3a. "Complete" means that all items required according to the record type, and in accordance with HCFA's record specifications and State required edits are in effect at the time the record is completed. In accordance with the final rule, facilities will be responsible to edit the encoded MDS data to ensure that it meets the standard edit specifications.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F287 (Cont.)	(i) Admission assessment. (ii) Annual assessment. (iii) Significant change in status assessment. (iv) Significant correction of prior full assessment. (v) Significant correction of prior quarterly assessment. (vi) Quarterly review. (vii) A subset of items upon a resident's transfer, reentry, discharge, and death. (viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment. (4) *Data format*. The facility must transmit data in the format specified by HCFA or, for a State which has an alternate RAI approved by HCFA, in the format specified by the State and approved by HCFA.	We encourage facilities to use software that has a programmed capability to automatically edit MDS records according to HCFA's edit specifications. For §483.20(f)(1)(v), the subset of items required upon a resident's transfer, discharge, and death are contained in the Discharge Tracking form and the items required for reentry are contained in the Reentry Tracking form. Refer to Appendix R for further information about the Discharge Tracking and Reentry Tracking forms. All nursing homes must computerize MDS information. The facility must edit MDS information using standard HCFA-specified edits, revise the information to conform to the edits and to be accurate, and be capable of transmitting that data to the State system within 7 days of: o completing a comprehensive assessment (the date at MDS item VB4); o completing an assessment that is not comprehensive (the date at MDS item R2b); o a discharge event (the date at MDS item R4); o a reentry event (the date at MDS item A4a); or o completing a correction request form (the date at MDS item AT6). Submission must be according to State and Federal time frames. Therefore the facility must: o Encode the MDS and RAP Summary (where applicable) in machine readable format;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F287 (Cont.)		o Edit the MDS and RAP Summary (where applicable) according to edits specified by HCFA. Within the 7 day time period specified above for editing, the facility must revise any information on the encoded MDS and RAP Summary (if applicable) that does not pass HCFA-specified edits, revise any otherwise inaccurate information, and make the information ready for submission. The MDS Vendor software used at the facility should have an automated editing process that alerts the user to entries in an MDS record that do not conform with the HCFA-specified edits and that prompts the facility to complete revisions within the 7 day editing and revision period. After editing and revision, MDS information and RAP summary information (if applicable) must always accurately reflect the resident's overall clinical status as of the original Assessment Reference date for an assessment or the original event date for a discharge or reentry; o Print the edited and revised MDS and RAP summary form (where applicable). Discharge or Reentry Tracking form or Correction Request form, and place it in the resident's record. The hard copy of the MDS record must match the record that the facility transmits to the State, and it must accurately reflect the resident's status as of the Assessment Reference date or event date. If a hard copy exists prior to data entry, the facility must correct the hard copy to reflect the changes associated with the editing and revision process. o Electronically submit MDS information to the State MDS database within 31 days of: o the date the Care Planning Decision process was complete (the date at MDS Item VB4) for comprehensive assessments; o the date the RN Coordinator certified that the MDS was complete (the date at MDS Item R2b) for assessments that are not comprehensive; o the date of death or discharge (the date at MDS Item R4) for Discharge Tracking forms; o the date of reentry (the date at MDS Item A4a) for Reentry Tracking forms; and o the date of completion of a correction request (the date at MDS Item AT6)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F287 (Cont.)		For a discussion of the process that a facility should follow in the event an error is discovered in an MDS record after editing and revision but before it is transmitted to the State, refer to *Correction Policy for MDS Records* in the State Operations Manual, Appendix R, Part IV. The facility must maintain RAI assessments and Discharge and Reentry Tracking forms, as well as correction information, including Correction Request forms as a part of the resident's clinical record. Whether or not the facility's system is entirely electronic, a hard copy of completed MDS forms, including the signature of the facility staff attesting to the accuracy and completion of the corrected record, must be maintained in the resident's clinical record. A facility must complete and submit to the State a subset of items when the resident is discharged from the facility (discharge tracking form), or readmitted to the facility (reentry tracking form.
Refer to F516	(5) *Resident-identifiable information*. (i) A facility may not release information that is resident-identifiable to the public. (ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.	§483.20(f)(5) Guidelines Automated RAI data are part of a resident's clinical record and as such are protected from improper disclosure by facilities under current law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and 42 CFR Part 483.75(l)(3) and (l)(4), to keep confidential all information contained in the resident's record and to maintain safeguards against the unauthorized use of a resident's clinical record information, regardless of the storage method of the records.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F278	(g) Accuracy of assessment. The assessment must accurately reflect the resident's status. (h) Coordination. A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals. (i) Certification. (1) A registered nurse must sign and certify that the assessment is completed. (2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment. (j) Penalty for falsification. (1) Under Medicare and Medicaid, an individual who willfully and knowingly-- (i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or (ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty or not more than $5,000 for each assessment. (2) Clinical disagreement does not constitute a material and false statement.	§483.20(g) Intent: To assure that each resident receives an accurate assessment by staff that are qualified to assess relevant care areas and knowledgeable about the resident's status, needs, strengths, and areas of decline. §483.20(g) Guidelines: "The accuracy of the assessment" means that the appropriate, qualified health professional correctly documents the resident's medical, functional, and psychosocial problems and identifies resident strengths to maintain or improve medical status, functional abilities, and psychosocial status. The initial comprehensive assessment provides baseline data for ongoing assessment of resident progress. §483.20(h) Intent: The registered nurse will conduct and/or coordinate the assessment, as appropriate. Whether conducted or coordinated by the registered nurse, he or she is responsible for certifying that the assessment has been completed. §483.20(h) Guidelines: According to the Utilization Guidelines for each State's RAI, the physical, mental and psychosocial condition of the resident determines the appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, medical social workers, dietitians, and other professionals, such as developmental disabilities specialists, in assessing the resident, and in correcting resident assessments. Involvement of other disciplines is dependent upon resident status and needs. §483.20(g)(h) Probes: o Have appropriate health professionals assessed the resident? For example, has the resident's nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident? o If the resident's medical status, functional abilities, or psychosocial status declined and the decline was not clinically unavoidable, were the appropriate health professionals involved in assessing the resident?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F278 (Cont.)		o Based on your total review of the resident, is each portion of the assessment accurate? o Are the appropriate certifications in place, including the RN Coordinator's certification of completion of an assessment or Correction Request form, and the certification of individual assessors of the accuracy and completion of the portion(s) of the assessment, tracking form or face sheet they completed or corrected. On an assessment or correction request, the RN Assessment Coordinator is responsible for certifying overall completion once all individual assessors have completed and signed their portion(s) of the MDS forms. When MDS forms are completed directly on the facility's computer, (e.g., no paper form has been manually completed), the RN Coordinator signs and dates the computer generated hard copy after reviewing it for completeness, including the signatures of all individual assessors. Backdating a completion date is not acceptable. §483.20(i) Guidelines: o Whether the MDS forms are manually completed, or computer generated following data entry, each individual assessor is responsible for certifying the accuracy of responses on the forms relative to the resident's condition and discharge or reentry status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the MDS record. When MDS forms are completed directly on the facility's computer (e.g., no paper form has been manually completed), then each individual assessor signs and dates a computer generated hard copy, after they review it for accuracy of the portion(s) they completed. Backdating completion dates is not acceptable. §483.20(j) Guidelines: o MDS information serves as the clinical basis for care planning and delivery. With the introduction of additional uses of MDS information such as for payment rate setting and quality monitoring, MDS information as it is reported impacts a nursing home's payment rate and standing in terms of the quality monitoring process. A pattern within a nursing home of clinical documentation or of MDS assessment or reporting practices that result in higher RUG scores, untriggering RAP(s), or unflagging QI(s), where the information does not accurately reflect the resident's status, may be indicative of payment fraud or avoidance of the quality monitoring process. Such practices may include but are not limited to a pattern or high prevalence of the following:

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F278 (Cont.)		- Submitting MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Reentry Tracking forms, where the information does not accurately reflect the resident's status as of the Assessment Reference date, or the Discharge or Reentry date, as applicable; - Submitting correction(s) to information in the State MDS database where the corrected information does not accurately reflect the resident's status as of the original Assessment Reference date, or the original Discharge or Reentry date, as applicable, or where the record it claims to correct does not appear to have been in error; - Submitting Significant Correction Assessments where the assessment it claims to correct does not appear to have been in error; - Submitting Significant Change in Status Assessments where the criteria for significant change in the resident's status do not appear to be met; - Delaying or withholding MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Reentry Tracking information, or correction(s) to information in the State MDS database. When such patterns or practices are noticed, they should be reported by the State Agency to the proper authority.
F279	k) Comprehensive care plans. (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following:	§483.20(k) Guidelines: An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The interdisciplinary team should show evidence in the RAP summary or clinical record of the following: o The resident's status in triggered RAP areas; o The facility's rationale for deciding whether to proceed with care planning; and o Evidence that the facility considered the development of care planning interventions for all RAPs triggered by the MDS.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F279 (Cont.)	(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and (ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).	The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to monitor resident progress. Facilities may, for some residents, need to prioritize their care plan interventions. This should be noted in the clinical record or on the plan or care. The requirements reflect the facility's responsibilities to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record (see guidelines at §483.10(b)(4) for additional guidance concerning refusal of treatment). §483.20(k)(1) Probes: o Does the care plan address the needs, strengths and preferences identified in the comprehensive resident assessment? o Is the care plan oriented toward preventing avoidable declines in functioning or functional levels? How does the care plan attempt to manage risk factors? Does the care plan build on resident strengths? o Does the care plan reflect standards of current professional practice? o Do treatment objectives have measurable outcomes? o Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents, especially those identified as refusing treatment. o Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment. o If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem? For implementation of care plan, see §483.20(k)(3).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F280	(2) A comprehensive care plan must be-- (i) Developed within 7 days after the completion of the comprehensive assessment; (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.	§483.20(k)(2) Guidelines: As used in this requirement, "Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) is at the discretion of the facility. The physician must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-on-one discussions and conference calls. The resident's right to participate in choosing treatment options, decisions in care planning and the right to refuse treatment are addressed at §483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse treatment. The facility has a responsibility to assist residents to participate, e.g., helping residents, and families, legal surrogates or representatives understand the assessment and care planning process; when feasible, holding care planning meetings at the time of day when a resident is functioning best; planning enough time for information exchange and decision making; encouraging a resident's advocate to attend (e.g. family member, friend) if desired by a resident. The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. (See §483.20(k)(2)(ii) and 483.10(b)(4).) The facility should encourage residents, legal surrogates and representatives to participate in care planning, including attending care planning conferences if they so desire. While Federal regulations affirm the resident's right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident, legal surrogate or representative to demand that the facility use specific medical intervention or treatment that the facility deems inappropriate. Statutory requirements hold the facility ultimately accountable for the resident's care and safety, including clinical decisions. §483.20(k)(2) Probes: 1. Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities? a. For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability? b. Do the dietitian and speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident? c. Is there evidence of physician involvement in development of the care plan (e.g., presence at care plan meetings, conversations with team members concerning the care plan, conference calls)? 2. In what ways do staff involve residents and families, surrogates, and/or representatives in care planning?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		3. Do staff make an effort to schedule care plan meetings at the best time of the day for residents and their families? 4. Ask the ombudsman if he/she has been involved in a care planning meeting as a resident advocate. If yes, ask how the process worked. 5. Do facility staff attempt to make the process understandable to the resident/family? 6. Ask residents whether they have brought questions or concerns about their care to the attention of facility's staff. If so, what happened as a result? §483.20(k)(2)(iii) Guidelines: See §483.75(g)(2)(iii) for "Qualified Person". §483.20(k)(2)(iii) Probes: o Is the care plan evaluated and revised as the resident's status changes?
F281	(3) The services provided or arranged by the facility must-- (i) Meet professional standards of quality and;	§483.20(k)(3)(i) Intent: The intent of this regulation is to assure that services being provided meet professional standards of quality (in accordance with the definition provided below) and are provided by appropriate qualified persons (e.g., licensed, certified).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		§483.20(k)(3)(i) Guidelines: "Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include: o Current manuals or textbooks on nursing, social work, physical therapy, etc. o Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc. o Clinical practice guidelines published by the Agency of Health Care Policy and Research. o Current professional journal articles. If a negative resident outcome is determined to be related to the facility's failure to meet professional standards, and the team determines a deficiency has occurred, it should be cited under the appropriate quality of care or other relevant requirement. §483.20(k)(3) Probes: Question only those practices which have a negative outcome or have a potential negative outcome. Ask the facility to produce references upon which the practice is based. o Do nurses notify physicians, as appropriate, and show evidence of discussions of acute medical problems? o Are residents with acute conditions who require intensive monitoring and hospital-level treatments that the facility is unable to provide, promptly hospitalized? o Are there errors in the techniques of medication administration? (Cite actual medication errors at §483.25(m).)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		o Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and comprehensive care plan? o Are physicians' orders carried out, unless otherwise indicated by an advanced directive?
F282	(ii) Be provided by qualified persons in accordance with each resident's written plan of care.	§483.20(k)(3)(ii) Guidelines: If you find problems with quality of care, quality of life, or resident rights, are these problems attributable to the qualifications of the facility staff, or lack of, inadequate or incorrect implementation of the care plan? §483.20(k)(3)(ii) Probes: o Can direct caregiving staff describe the care, services, and expected outcomes of the care they provide; have a general knowledge of the care and services being provided by other therapists; have an understanding of the expected outcomes of this care, and understand the relationship of these expected outcomes to the care they provide?
F283	(l) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes: (1) A recapitulation of the resident's stay; (2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and	§483.20(l) Intent: To ensure appropriate discharge planning and communication of necessary information to the continuing care provider. §483.20(l) Guidelines: "Anticipates" means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition) or due to the resident's death.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F284	(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.	"Adjust to his or her living environment" means that the post-discharge plan, as appropriate, should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple caregivers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/caregiver education needs and ability to meet care needs after discharge. §483.20(l)(3) Guidelines A post-discharge plan of care for an anticipated discharge applies to a resident whom the facility discharges to a private residence, to another NF or SNF, or to another type of residential facility such as a board and care home or an intermediate care facility for individuals with mental retardation. Resident protection concerning transfer and discharge are found at §483.12. A "post-discharge plan of care" means the discharge planning process which includes: assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community. §483.20(l) Probes: o Does the discharge summary have information pertinent to continuing care for the resident? o Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)? o Do discharge plans address necessary post-discharge care? o Has the facility aided the resident and his/her family in locating and coordinating post-discharge services? o What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F285	(m) *Preadmission screening for mentally ill individuals and individuals with mental retardation*. (1) A nursing facility must not admit, on or after January 1, 1989, any new residents with-- (i) Mental illness as defined in paragraph (m)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission; (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and (B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation. (ii) Mental retardation, as defined in paragraph (m)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission-- (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and	§483.20(m) Intent: To ensure that individuals with mental illness and mental retardation receive the care and services they need in the most appropriate setting. "Specialized services" are those services the State is required to provide or arrange for that raise the intensity of services to the level needed by the resident. That is, specialized services are an "add-on" to NF services--they are of a higher intensity and frequency than specialized rehabilitation services, which are provided by the NF. The statute mandates preadmission screening for all individuals with mental illness (MI) or mental retardation (MR) who apply to NFs, regardless of the applicant's source of payment, except as provided below. (See §1919(b)(3)(F).) Residents readmitted and individuals who initially apply to a nursing facility directly following a discharge from an acute care stay are exempt if: o They are certified by a physician prior to admission to require a nursing facility stay of less than 30 days; and o They require care at the nursing facility for the same condition for which they were hospitalized. The State is responsible for providing specialized services to residents with MI/MR residing in Medicaid-certified facilities. The facility is required to provide all other care and services appropriate to the resident's condition. Therefore, if a facility has residents with MI/MR, do not survey for specialized services, but survey for all other requirements, including resident rights, quality of life, and quality of care. If the resident's PAS report indicates that he or she needs specialized services but the resident is not receiving them, notify the Medicaid agency. NF services ordinarily are not of the intensity to meet the needs of residents with MI or MR.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation. (2) Definitions. For purposes of this section-- (i) An individual is considered to have "mental illness" if the individual has a serious mental illness defined at 483.102(b)(1). (ii) An individual is considered to be "mentally retarded" if the individual is mentally retarded as defined in 483.102(b)(3) or is a person with a related condition as described in 42 CFR 1009.	§483.20(m) Probes: If sampled residents have MI or MR, did the State Mental Health or Mental Retardation Authority determine: o Whether the residents needed the services of a NF? o Whether the residents need specialized services for their MR or MI?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Quality of Care	Guidelines: §483.25
F309	Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Use F309 for quality of care deficiencies not covered by §483.25(a)-(m).	Use F309 when the survey team determines there are quality of care deficiencies not covered by §§483.25(a)-(m). "Highest practicable" is defined as the highest level of functioning and well-being possible, limited only by the individual's presenting functional status and potential for improvement or reduced rate of functional decline. Highest practicable is determined through the comprehensive resident assessment by competently and thoroughly addressing the physical, mental or psychosocial needs of the individual. The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process. In any instance in which there has been a lack of improvement or a decline, the survey team must determine if the occurrence was unavoidable or avoidable. A determination of unavoidable decline or failure to reach highest practicable well-being may be made only if all of the following are present: o An accurate and complete assessment (see §483.20); o A care plan which is implemented consistently and based on information from the assessment; o Evaluation of the results of the interventions and revising the interventions as necessary. Determine if the facility is providing the necessary care and services based on the findings of the RAI. If services and care are being provided, determine if the facility is evaluating the outcome to the resident and changing the interventions if needed. This should be done in accordance with the resident's customary daily routine. Use Tag F309 to cite quality of care deficiencies that are not explicit in the quality of care regulations. Procedures: §483.25 Assess a facility's compliance with these requirements by determining if the services noted in the plan of care, based on a comprehensive and accurate functional assessment of the resident's strengths, weaknesses, risk factors for deterioration and potential for improvement, is continually and aggressively implemented and updated by the facility staff. In looking at assessments, use both the MDS and RAPs information, any other pertinent assessments, and resulting care plans. If the resident has been in the facility for less than 14 days (before completion of all the RAI is required), determine if the facility is conducting ongoing assessment and care planning, and, if appropriate, care and services are being provided. If quality of care problems are noted in areas of nurse aide responsibility, review nurse aide competency requirements at §483.75(e).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(a) Activities of daily living. Based on the comprehensive assessment of a resident, the facility must ensure that	Intent: §483.25(a) The intent of this regulation is that the facility must ensure that a resident's abilities in ADLs do not deteriorate unless the deterioration was unavoidable.
F310	(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to- - (i) Bathe, dress, and groom; (ii) Transfer and ambulate; (iii) Toilet; (iv) Eat; and (v) Use speech, language, or other functional communication systems.	Guidelines: §483.25(a) The mere presence of a clinical diagnosis, in itself, justify a decline in a resident's ability to perform ADLs. Conditions which may demonstrate unavoidable diminution in ADLs include: o The natural progression of the resident's disease; o Deterioration of the resident's physical condition associated with the onset of a physical or mental disability while receiving care to restore or maintain functional abilities; and o The resident's or his/her surrogate's or representative's refusal of care and treatment to restore or maintain functional abilities after aggressive efforts by the facility to counsel and/or offer alternatives to the resident, surrogate, or representative. Refusal of such care and treatment should be documented in the clinical record. Determine which interventions were identified on the care plan and/or could be in place to minimize or decrease complications. Note also that depression is a potential cause of excess disability and, where appropriate, therapeutic interventions should be initiated. Appropriate treatment and services includes all care provided to residents by employees, contractors, or volunteers of the facility to maximize the individual's functional abilities. This includes pain relief and control, especially when it is causing a decline or a decrease in the quality of life of the resident. If the survey team identifies a pattern of deterioration in ADLs, i.e., a number of residents have deteriorated in more than one ADL or a number of residents have deteriorated in only one ADL (one in bathing, one in eating, one in toileting) and it is determined there is deficient practice, cite at F310. For evaluating a resident's ADLs and determining whether a resident's abilities have declined, improved or stayed the same within the last twelve months, use the following definitions as specified in the State's RAI: 1. Independent - No help or staff oversight; or staff help/oversight provided only 1 or 2 times during prior 7 days. 2. Supervision - Oversight encouragement or cuing provided 3 or more times during the last 7 days, or supervision plus physical assistance provided only 1 or 2 times during the last 7 days.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F310 Cont.		3. Limited Assistance - Resident highly involved in activity, received physical help in guided maneuvering of limbs, and/or other non-weight bearing assistance 3 or more times; or more help provided only 1 or 2 times over 7-day period. 4. Extensive Assistance - While resident performed part of activity, over prior 7-day period, help of following type(s) was provided 3 or more times; a.Weight-bearing support; or b.Full staff performance during part (but not all) of week. 5. Total Dependence - Full staff performance of activity over entire 7-day period. BATHING, DRESSING, GROOMING Guidelines: §483.25(a)(1)(i) This corresponds to MDS section E; version 2.0, section G, when specified for use by the State. "Bathing" means how resident takes full-body bath, sponge bath, and transfers in/out of tub/shower. Exclude washing of back and hair. "Dressing" means how resident puts on, fastens, and takes off all items of clothing, including donning/removing prosthesis. "Grooming" means how resident maintains personal hygiene, including preparatory activities, combing hair, brushing teeth, shaving, applying make-up, washing/drying face, hands and perineum. Exclude baths and showers. Procedures: §483.25(a)(1)(i) BATHING, DRESSING, GROOMING For each sampled resident selected for the comprehensive review or the focused review, as appropriate, determine: 1. Whether the resident's ability to bathe, dress and/or groom has changed since admission, or over the past 12 months; 2. Whether the resident's ability to bathe, dress and groom has improved, declined or stayed the same; 3. Whether any deterioration or lack of improvement was avoidable or unavoidable by: 4. Identifying if resident triggers RAPs for ADL functional/rehabilitation potential. a. What risk factors for decline of bathing, dressing, and/or grooming abilities did the facility identify? b. What care did the resident receive to address unique needs to maintain his/her bathing, dressing, and/or grooming abilities (e.g., resident needs a button hook to button his shirt; staff teaches the resident how to use it; staff provides resident with dementia with cues that allow him/her to dress him or herself)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F310 Cont.		c. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of bathing, dressing, and/or grooming abilities (e.g., resident now unable to button dress, even with encouragement; will ask family if we may use velcro in place of buttons so resident can continue to dress herself)? Probes: §483.25(a)(1)(i) If the resident's abilities in bathing, dressing, and grooming have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided: o Identify relevant sections of the MDS and consider whether assessment triggers the RAPs and the RAPs were followed. o Are there physical and psychosocial deficits that could affect improvement in functional abilities? o Was the care plan driven by resident strengths identified in the comprehensive assessment? o Was the care plan consistently implemented? What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress might have been possible?
		TRANSFER AND AMBULATION Guidelines: §483.25(a)(1)(ii) This corresponds to MDS section E; MDS 2.0 section G when specified for use by the State. "Transfer" means how resident moves between surfaces - to/from: bed, chair, wheelchair, standing position. (Exclude to/from bath/toilet.) "Ambulation" means how resident moves between locations in his/her room and adjacent corridor on same floor. If in wheelchair, self-sufficiency once in chair. Procedures: §483.25(a)(1)(ii) TRANSFER AND AMBULATION Determine for each resident selected for a comprehensive review, or a focused review as appropriate, whether the resident's ability to transfer and ambulate has declined, improved or stayed the same and whether any deterioration or decline in function was avoidable or unavoidable. Probes: §483.25(a)(1)(ii) If the resident's transferring and ambulating abilities have declined, what evidence is there that the decline was unavoidable: o What risk factors for decline of transferring or ambulating abilities did the facility identify (e.g., necrotic area of foot ulcer becoming larger, postural hypotension)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F310 Cont.		o What care did the resident receive to address risk factors and unique needs to maintain transferring or ambulating abilities (e.g., a transfer board is provided to maintain ability to transfer from bed to wheelchair and staff teaches the resident how to use it)? o What evidence is there that sufficient staff time and assistance are provided to maintain transferring and ambulating abilities? o Has resident been involved in activities that enhance mobility skills? o Were individual objectives of the plan of care periodically evaluated, and if goals were not met, were alternative approaches developed to encourage maintenance of transferring and ambulation abilities (e.g., resident remains unsteady when using a cane, returns to walker, with staff encouraging the walker's consistent use)? o Identify if resident triggers RAPs for ADL functional/rehabilitation potential, psychosocial well-being, or mood state and the RAPs are followed. If the resident's abilities in transferring and ambulating have been maintained, is there evidence that the resident could have improved if appropriate treatment and services were provided? o Are there physical and psychosocial deficits that could affect improvement in functional abilities? o Was the care plan driven by resident strengths identified in the comprehensive assessment? o Was the care plan consistently implemented? What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible? TOILETING Guidelines: §483.25(a)(1)(iii) This corresponds to MDS sections E; MDS 2.0 sections G and H when specified for use by the State. "Toilet use" means how the resident uses the toilet room (or commode, bedpan, urinal); transfers on/off the toilet, cleanses self, changes pad, manages ostomy or catheter, adjusts clothes. Procedures: §483.25(a)(1)(iii) TOILETING Determine for each resident selected for a comprehensive review, or focused review as appropriate, whether the resident's ability to use the toilet has improved, declined or stayed the same and whether any deterioration or decline in improvement was avoidable or unavoidable. Probes: §483.25(a)(1)(iii) TOILETING If the resident's toilet use abilities have declined, what evidence is there that the decline was unavoidable.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F310 Cont.		o What risk factors for the decline of toilet use abilities did the facilityidentify (e.g., severe arthritis in hands makes use of toilet paper difficult)? o What care did resident receive to address risk factors and unique needs to maintain toilet use abilities (e.g., assistive devices to maintain ability to use the toilet such as using a removable elevated toilet seat or wall grab bar to facilitate rising from seated position to standing position)? o Is there sufficient staff time and assistance provided to maintain toilet use abilities (e.g., allowing residents enough time to use the toilet independently or with limited assistance)? o Were individual objectives of the plan of care periodically evaluated, and if objectives were not met, were alternative approaches developed to encourage maintaining toilet use abilities (e.g., if resident has not increased sitting stability, seek occupational therapy consult to determine the need for therapy to increase sitting balance, ability to transfer safely and manipulate clothing during the toileting process. For residents with dementia, remind periodically to use the toilet)? o Identify if resident triggers RAPs for urinary incontinence, and ADL functional/rehabilitation potential and the RAPs were used to assess causal factors for decline or potential for decline or lack of improvement. If the resident's toilet use abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided? o Are there physical and psychosocial deficits that could affect improvement in functional abilities? o Was the care plan driven by resident strengths identified in the comprehensive assessment? o Was the care plan consistently implemented? What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible? o Identify if resident triggers RAPs for mood state and psychosocial well-being. EATING Guidelines: §483.25(a)(1)(iv) This corresponds to MDS sections E, L1 and MI; MDS 2.0 sections G and K when specified for use by the State. "Eating" means how resident ingests and drinks (regardless of self-feeding skill). Procedures: §483.25(a)(1)(iv) EATING Determine for each resident selected for a comprehensive review, or focused review, as appropriate, whether the resident's ability to eat or eating skills has improved, declined, or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F310 Cont.		If the resident's eating abilities have declined, is there any evidence that the decline was unavoidable? 1. What risk factors for decline of eating skills did the facility identify? a. A decrease in the ability to chew and swallow food b. Deficit in neurological and muscular status necessary for moving food onto a utensil and into the mouth c. Oral health status affecting eating ability d. Depression or confused mental state 2. What care did the resident receive to address risk factors and unique needs tomaintain eating abilities? a. Assistive devices to improve resident's grasp or coordination b. Seating arrangements to improve sociability c. Seating in a calm, quiet setting for residents with dementia 3. Is there sufficient staff time and assistance provided to maintain eating abilities (e.g., allowing residents enough time to eat independently or with limited assistance)? 4. Identify if resident triggers RAPs for ADL functional/rehabilitation potential, feeding tubes, and dehydration/fluid maintenance, and the RAPs were used to assess causal reasons for decline, potential for decline or lack of improvement. 5. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintaining eating abilities? Probes: §483.25(a)(1)(iv) If the resident's eating abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided: o Are there physical and psychosocial deficits that could affect improvement in functional abilities? o Was the care plan driven by resident strengths identified in the comprehensive assessment? o Was the care plan consistently implemented? What changes are made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible? USE OF SPEECH, LANGUAGE, OR OTHER FUNCTIONAL COMMUNICATION SYSTEMS Guidelines: §483.25(a)(1)(v) This corresponds to MDS, section C; MDS 2.0 sections B and C when specified for use by the State. "Speech, language or other functional communication systems" is defined as the ability to effectively communicate requests, needs, opinions, and urgent problems; to express emotion, to listen to others and to participate in social conversation whether in

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F310 Cont		speech, writing, gesture or a combination of these (e.g., a communication board or electronic augmentative communication device). Procedures: §483.25(a)(1)(v) USE OF SPEECH, LANGUAGE OR OTHER FUNCTIONAL COMMUNICATION SYSTEMS Determine for each resident selected for a comprehensive review, or focused review, as appropriate, if resident's ability to communicate has declined, improved or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable. o Identify if resident triggers RAPs for communication, psychosocial well-being,mood state, and visual function, and if the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement. Probes: §483.25(a)(1)(v) If the resident's communication abilities have diminished, is there any evidence that the decline was unavoidable: o What risk factors for decline of communication abilities did the facility identify and how did they address them (e.g., dysarthria, poor fitting dentures, few visitors, poor relationships with staff, Alzheimer's disease)? o Has the resident received audiologic and vision evaluation? If not, did the resident refuse such services? (See also §483.10(b)(4).) o What unique resident needs and risk factors did the facility identify (e.g., does the resident have specific difficulties in transmitting messages, comprehending messages, and/or using a variety of communication skills such as questions and commands; does the resident receive evaluation and training in the use of assistive devices to increase and/or maintain writing skills)? o What care does the resident receive to improve communication abilities (e.g.,nurse aides communicate in writing with deaf residents or residents with severe hearing problems; practice exercises with residents receiving speech-language pathology services; increase number of resident's communication opportunities; non-verbal means of communication; review of the effect of medications on communication ability)? o Is there sufficient staff time and assistance provided to maintain communication abilities? o Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of communication abilities (e.g., if drill-oriented therapy is frustrating the resident, a less didactic approach should be attempted)? Probes: §483.25(a)(1)(v) USE OF SPEECH, LANGUAGE OR OTHER FUNCTIONAL COMMUNICATION SYSTEMS If the resident's speech, language, and other communication abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided: o Are there physical and psychosocial deficits that could affect improvement in functional abilities? o Was the care plan driven by resident strengths identified in the comprehensive assessment?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F311	(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and	o Was the care plan consistently implemented? What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible? Intent: §483.25(a)(2) The intent of this regulation is to stress that the facility is responsible for providing maintenance and restorative programs that will not only maintain, but improve, as indicated by the resident's comprehensive assessment to achieve and maintain the highest practicable outcome. Procedures: §483.25(a)(2) Use the survey procedures and probes at §483.25(a)(1)(i) through (v) to assist in making this determination
F312	(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.	Intent: §483.25(a)(3) The intent of this regulation is that the resident receives the care and services needed because he/she is unable to do their own ADL care independently. Guidelines: §483.25(a)(3) This corresponds to MDS section L; MDS 2.0 section K when specified by the State. "Unable to carry out ADLs" means those residents who need extensive or total assistance with maintenance of nutrition, grooming and personal and oral hygiene, receive this assistance from the facility. Methods for maintenance of good nutrition may include hand feeding of foods served on dishes; tube feedings provided through naso-gastric, gastrostomy, or other external tubes; or total parenteral nutrition provided through a central intravenous line. "Grooming": See §483.25(a)(1)(i) for definition. "Personal hygiene": Those activities described in dressing and bathing as defined in §483.25(a)(1)(i). "Oral hygiene" means maintaining the mouth in a clean and intact condition and treating oral pathology such as ulcers of the mucosa. Services to maintain oral hygiene may include brushing the teeth, cleaning dentures, cleaning the mouth and tongue either by assisting the resident with a mouth wash or by manual cleaning with a gauze sponge; and application of medication as prescribed.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F312 Cont.		Procedures: §483.25(a)(3) For residents selected for a comprehensive review, or focused review, as appropriate, who are unable to carry out these ADLs without extensive assistance, determine if poor nutritional status, poor grooming, or lack of effective personal and oral hygiene exist. To what extent are these negative outcomes attributable to the lack of receiving necessary services? Identify if residents trigger RAPs for nutritional status, ADL functional/rehabilitation potential, behavior problems, and dental care. Consider whether the RAPs were used to assess causal factors for decline, potential for decline, or lack of improvement. Determine if the facility proceeded properly with care planning and delivery of care for these residents
F313	(b) Vision and hearing. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident-- (1) In making appointments, and (2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing	Intent: §483.25(b) The intent of this regulation is to require a facility to assist residents in gaining access to vision and hearing services by making appointments and arranging for transportation, and assistance with the use of any devices needed to maintain vision and hearing. Guidelines: §483.25(b) This corresponds to MDS, sections C and O; MDS 2.0 sections C, D and P when specified for use by the State. Assistive devices to maintain vision include glasses, contact lenses, and magnifying glasses. Assistive devices to maintain hearing include hearing aids. This requirement does not mean that the facility must provide refractions, glasses, contact lenses, conduct comprehensive audiological evaluations (although screening is a part of the required assessment in §483.20(b)) or provide hearing aids. The facility's responsibility is to assist residents and their families in locating and utilizing any available resources (e.g., Medicare or Medicaid program payment, local health organizations offering items and services which are available free to the community) for the provision of the services the resident needs. This includes making appointments and arranging transportation to obtain needed services. Probes: §483.25(b) o Identify if resident triggers RAPs for visual function, and communication. Consider whether the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement. o If the resident needs, and/or requests and does not have vision and/or hearing assistive devices, what has the facility done to assist the resident in making appointments and obtaining transportation to obtain these services?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F313 Cont.		o If the resident has assistive devices but is not using them, why not (e.g., are repairs or batteries needed)?
F314	(c) Pressure sores. Based on the comprehensive Assessment of a resident, the facility must ensure that- - (1) A resident who enters the facilit without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and	Intent: §483.25(c) The intent of this regulation is that the resident does not develop a pressure sore while in the facility. If the resident is admitted with or develops a pressure sore, he or she receives care and treatment to heal and prevent further development of pressure sores. For additional information on prevention, staging and treatment, refer to the staging system found in the booklet "Pressure Ulcers in Adults: Prevention and Treatment, Public Health Service Agency for Health Care Policy and Research." Guidelines: §483.25(c) This corresponds to MDS, section N; MDS 2.0 section I, M and P when specified for use by the State. "Pressure sore" means ischemic ulceration and/or necrosis of tissues overlying a bony prominence that has been subjected to pressure, friction or shear. The staging system presented below is one method of describing the extent of tissue damage in the pressure sore. Pressure sores cannot be adequately staged when covered with eschar or necrotic tissue. Staging should be done after the eschar has sloughed off or the wound has been debrided. Vascular ulcers due to Peripheral Vascular Disease (PVD) have to be considered separately. They usually occur on the lower legs and feet and are very persistent even with aggressive treatment. Stage I: A persistent area of skin redness (without a break in the skin) that is nonblanchable. Redness can be expected to be present for one-half to three-fourths as long as the pressure applied that has occluded blood flow to the areas. For example: If a resident is laying on his right side for 30 minutes and turned to his back, redness may be noticed over his right hip bone. Redness in that area can be expected to remain for up to 20 minutes. The survey team then would check to see if the area is nonblanchable. Just having the redness does not indicate a stage I. To identify the presence of stage I pressure ulcers in residents with darkly pigmented skin, look for changes such as changes in skin color (grayish hue), temperature, swelling, and tenderness or texture. Stage II: A partial thickness loss of skin layers either dermis or epidermis that presents clinically as an abrasion, blister, or shallow crater. Stage III: A full thickness of skin is lost, exposing the subcutaneous tissues - presents as a deep crater with or without undermining adjacent tissue. Stage IV: A full thickness of skin and subcutaneous tissue is lost, exposing muscle and/or bone. Procedures: §483.25(c) Identify if resident triggers RAPs for urinary incontinence, nutritional status, cognitive loss/dementia, psychotropic drug use, and physical restraints. Consider

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F314 Cont.		whether the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement. If the resident is moribund (i.e., the resident is terminally ill; semi - comatose or comatose) and life - sustaining measures havebeen withdrawn or discouraged as documented in the record, pressure sores may be clinically difficult to prevent. A determination that development of a pressure sore was unavoidable may be made only if routine preventive and daily care was provided. Routine preventive care means turning and proper positioning, application of pressure reduction or relief devices, providing good skin care (i.e., keeping the skin clean, instituting measures to reduce excessive moisture), providing clean and dry bed linens, and maintaining adequate nutrition and hydration as possible Clinical conditions that are the primary risk factors for developing pressure sores include, but are not limited to, resident immobility and: 1. The resident has two or more of the following diagnoses: a. Continuous urinary incontinence or chronic voiding dysfunction; b. Severe peripheral vascular disease; c. Diabetes; d. Severe chronic pulmonary obstructive disease; e. Severe peripheral vascular disease; f. Chronic bowel incontinence; g. Continuous urinary incontinence or chronic voiding dysfunction; h. Paraplegia; i. Quadriplegia; j. Sepsis; k. Terminal cancer; l. Chronic or end stage renal, liver, and/or heart disease; m. Disease or drug-related immunosuppression; or n. Full body cast. 2. The resident receives two or more of the following treatments: a. Steroid therapy; b. Radiation therapy; c. Chemotherapy; d. Renal dialysis; or e. Head of bed elevated the majority of the day due to medical necessity. 3. Malnutrition/dehydration, whether secondary to poor appetite or another disease process, places resident at risk for poor healing, and may be indicated by the following lab values: a. Serum albumin below 3.4 g/dl b. Weight loss of more than 10% during last month

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F314 Cont.		c. Serum transferrin level below 180 mg per dl d. Hgb less than 12 mg per dl. Use these values in conjunction with an evaluation of the resident's clinical condition. 4. If laboratory data are not available, clinical signs and symptoms of malnutrition/dehydration may be: a. Pale skin; b. Red, swollen lips; c. Swollen and/or dry tongue with scarlet or magenta hue; d. Poor skin turgor; e. Cachexia; f. Bilateral edema; g. Muscle wasting; h. Calf tenderness; or i. Reduced urinary output. Probes: §483.25(c)(1) For each sampled resident selected for the comprehensive review, or the focused review at risk of developing pressure sores, determine, as appropriate, if aggressive preventive care is provided? For sampled residents, who upon initial admission to the facility, did not have a pressure sore and now have one, determine if pressure sore development may have been avoided: o Did the facility identify the resident as being at risk for pressure sore(s)? o Did the facility provide aggressive/appropriate preventive measures and care specific to addressing the resident's unique risk factors (e.g., if serum albumin is below 3.4 mg per dl, provide additional protein in daily snacks)? o Was this preventive care plan implemented consistently?
	(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing	Probes: 483.25 (c)(2) For all sampled residents who have pressure sores at the time of the survey, including those readmitted from the hospital with a pressure sore that developed in the hospital: o Are measures to assist healing provided per the plan of care (e.g., relieving pressure, moving the resident without causing shearing, instituting topical therapy which creates a favorable environment for healing, and debriding eschar? o Are measures to prevent further contamination followed (e.g., wash hands before caring for sore? Observe clean or sterile technique, as indicated, when dressing is changed). All wounds are contaminated (soiled/contain organisms). An infected wound is accompanied by local or systemic symptoms. Clean technique is adequate when caring for a non-infected wound

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(d) Urinary Incontinence. Based on the resident's comprehensive assessment, the facility must ensure that--	o Are universal precautions used during all wound care? (See §483.65, Infection Control.) o Have the care plan objectives been evaluated? If the pressure sore is not healing, getting larger, or signs of additional skin breakdown are evident, have alternative interventions been considered or attempted? o Has improvement been noted?
F315	(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and	Guidelines: §483.25(d)(1) This corresponds to MDS section F; MDS 2.0 sections G and H when specified by the State. Intent: §483.25(d)(1) The intent of this regulation is to ensure that an indwelling catheter is only to be used when there is valid medical justification. The resident should be assessed for and provided the care and treatment needed to reach his or her highest level of continence possible. The facility is expected to show evidence of any medical factors which caused the intervention. Examples of clinical conditions demonstrating that catheterization may be unavoidable include: 1. Urinary retention that: a. Is causing persistent overflow incontinence, symptomatic infections, and/or renal dysfunction; b. Cannot be corrected surgically; or c. Cannot be managed practically with intermittent catheter use. 2. Skin wounds, pressure sores, or irritations that are being contaminated by urine; 3. Terminal illness or severe impairment, which makes bed and clothing changes uncomfortable or disruptive (i.e., as in the case of intractable pain). Probes: §483.25(d)(1) For sampled residents selected for a comprehensive or focused review who entered the facility without a catheter and are now catheterized, determine as appropriate if the use of an indwelling catheter was unavoidable. o Was the resident continent upon admission? o If continent at admission, was the resident identified as having risk factors of incontinence (e.g., frequency of urination, with limited mobility)? o What care did the resident receive to promote maintenance of continence? o Did the facility attempt to manage the incontinence and increase bladder function without the use of an indwelling catheter (e.g., a bladder training program, prompted voiding schedule, external catheter)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F316	(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.	o Identify if resident triggers RAPs for urinary incontinence, ADL functional/rehabilitation potential, and cognitive loss/dementia and the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement. If the resident has an indwelling catheter: o Is the staff following the facility's protocol and/or written procedures for catheterization? o Do all personnel wash their hands before and after caring for the catheter/tubing/collecting bag? o Does the facility assess for continued need for use of the catheter, as appropriate, utilizing the evaluative data as described and implemented in the care plan? Guidelines: §483.25(d)(2) For purposes of this regulation, "urinary tract infection (UTI)" is defined as colonization (growth of bacteria) of the urinary tract with signs or symptoms of UTI. Asymptomatic colonization is not a UTI. Care should be provided based on the type, severity, and cause (if known) of the urinary incontinence. Antibiotic therapy should be reserved for residents with active symptoms of UTI. Routine and overzealous use could lead to resistance of organisms. Probes: §483.25(d)(2) For each incontinent sampled resident selected for the comprehensive, or focused review determine, as appropriate: o Has the facility identified (or attempted to identify) the cause of the incontinence? o Is the resident adequately hydrated? o How many residents currently have a UTI? Differentiate between bacterial colonization vs. acute infection. (See also §483.65, Infection Control.) o Are risk factors for UTI monitored and managed (e.g., poor fluid intake, previous UTIs)? Are residents with a history of UTI adequately assessed and provided care and treatment to prevent UTI? o Are infection control procedures in place (e.g., adequate fluid intake)? o What care did the resident receive, consistent with the comprehensive assessment, to restore or improve bladder functioning (e.g., pelvic floor exercises, habit training, or maintaining adequate hydration)? o Have the individualized goals of this treatment program been evaluated periodically, and if goals were not reached, have alternative goals and approaches been developed? o If staff determine that continence cannot be improved or maintained, has a plan been implemented to prevent incontinent-related complications and to maintain resident dignity (e.g., skin care will be provided after each episode of incontinence, adult sanitary padding will be worn at all times when the resident is out of bed)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F 316 Cont.		
		o Identify if resident triggers RAPs for urinary incontinence, ADL functional/rehabilitation potential, and dehydration/fluid maintenance. Consider whether the RAPs were used to assess causal factors for decline, potential for decline, or lack of improvement.
	(e) Range of motion. Based on the comprehensive assessment of a resident, the facility must ensure that--	Intent: §483.25(e) The intent of this regulation is to ensure that the resident reaches and maintains his or her highest level of range of motion and to prevent avoidable decline of range of motion.
F317	(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and	Guidelines: §483.25(e) This corresponds to MDS section E; MDS 2.0 sections G and P when specified for use by the State. "Range of motion (ROM)" is defined as the extent of movement of a joint. The clinical condition that may demonstrate that a reduction in ROM is unavoidable is: limbs or digits immobilized because of injury or surgical procedures (e.g., surgical adhesions).
F318	(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion	Adequate preventive care may include active ROM performed by the resident's passive ROM performed by staff; active-assistive ROM exercise performed by the resident and staff; and application of splints and braces, if necessary. Examples of clinical conditions that are the primary risk factors for a decreased range of motion are: o Immobilization (e.g., bedfast); o Deformities arising out of neurological deficits (e.g., strokes, multiple sclerosis, cerebral palsy, and polio); and o Pain, spasms, and immobility associated with arthritis or late state Alzheimer's disease. This clinical condition may demonstrate that a reduction in ROM is unavoidable only if adequate assessment, appropriate care planning, and preventive care was provided, and resulted in limitation in ROM or muscle atrophy.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F318 Cont.		Procedures: §483.25(e) For each resident selected for a comprehensive review, or focused review, as appropriate, who needs routine preventive care: o Observe staff providing routine ROM exercises. Are they done according to the care plan? Probes: §483.25(e) Is there evidence that there has been a decline in sampled residents' ROM or muscle atrophy that was avoidable? o Was the resident at risk for decline in ROM? If so, why? o What care did the facility provide, including routine preventive measures thataddressed the resident's unique risk factors (e.g., use muscle strengthening exercises in residents with muscle atrophy)? o Was this care provided consistently? For all sampled residents who have limited ROM, what is the facility doing to prevent further declines in ROM? o Are passive ROM exercises provided and active ROM exercises supervised per theplan of care? o Have care plan objectives identified resident's needs and has resident progress been evaluated? o Is there evidence that care planning is changed as the resident's condition changes? o Identify if resident triggers RAPs for ADL functional/rehabilitation potential, visual function, and communication. Consider whether the RAPs used to assess causal factors for decline, potential for decline or lack of improvement.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(f) Mental and Psychosocial functioning. Based on the comprehensive assessment of a resident, the facility must ensure that--	Intent: §483.25(f) The intent of this regulation is that the resident receives care and services to assist him or her to reach and maintain the highest level of mental and psychosocial functioning.
F319	(1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem; and	Guidelines: §483.25(f) This corresponds to MDS, sections G, J and P1; MDS 2.0 sections B, F, E, and I when specified for use by the State. "Mental and psychosocial adjustment difficulties" refer to problems residents have in adapting to changes in life's circumstances. The former focuses on internal thought processes; the latter, on the external manifestations of these thought patterns. Mental and psychosocial adjustment difficulties are characterized primarily by an overwhelming sense of loss of one's capabilities; of family and friends; of the ability to continue to pursue activities and hobbies; and of one's possessions. This sense of loss is perceived as global and uncontrollable and is supported by thinking patterns that focus on helplessness and hopelessness; that all learning and essentially all meaningful living ceases once one enters a nursing home. A resident with a mental adjustment disorder will have a sad or anxious mood, or a behavioral symptom such as aggression. The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM/IV), specifies that adjustment disorders develop within 3 months of a stressor (e.g., moving to another room) and are evidenced by significant functional impairment. Bereavement with the death of a loved one is not associated with adjustment disorders developed within 3 months of a stressor. Other manifestations of mental and psychosocial adjustment difficulties may, over a period of time, include: o Impaired verbal communication; o Social isolation (e.g., loss or failure to have relationships); o Sleep pattern disturbance (e.g., disruptive change in sleep/rest pattern asrelated to one's biological and emotional needs); o Spiritual distress (disturbances in one's belief system); o Inability to control behavior and potential for violence (aggressive behavior directed at self or others); and o Stereotyped response to any stressor (i.e., the same characteristic response, regardless of the stimulus). Appropriate treatment and services for psychosocial adjustment difficulties may include providing residents with opportunities for self-governance; systematic orientation programs; arrangements to keep residents in touch with their communities, cultural heritage, former lifestyle, and religious practices; and maintaining contact with friends and family

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F319 Cont.		Appropriate treatment for mental adjustment difficulties may include crisis intervention services; individual, group or family psychotherapy, drug therapy and training in monitoring of drug therapy and other rehabilitative services. (See §483.45(a).) Clinical conditions that may produce apathy, malaise, and decreased energy levels that can be mistaken for depression associated with mental or psychosocial adjustment difficulty are: (This list is not all inclusive.) o Metabolic diseases (e.g., abnormalities of serum glucose, potassium, calcium, and blood urea nitrogen, hepatic dysfunction); o Endocrine diseases (e.g., hypothyroidism, hyperthyroidism, diabetes, hypoparathyroidism, hyperparathyroidism, Cushing's disease, Addison's disease); o Central nervous system diseases (e.g., tumors and other mass lesions, Parkinson's disease, multiple sclerosis, Alzheimer's disease, vascular disease); o Miscellaneous diseases (e.g., pernicious anemia, pancreatic disease, malignancy, infections, congestive heart failure); o Over-medication with anti-hypertensive drugs; and o Presence of restraints. Probes: §483.25(f)(1) For sampled residents selected for a comprehensive or focused review, determine, as appropriate, for those residents exhibiting difficulties in mental and psychosocial adjustment: o Is there a complete accurate assessment of resident's usual and customary routines? o What evidence is there that the facility makes accommodations for the resident's usual and customary routines? o What programs/activities has the resident received to improve and maintain maximum mental and psychosocial functioning? o Has the resident's mental and psychosocial functioning been maintained or improved (e.g., fewer symptoms of distress)? Have treatment plans and objectives been re-evaluated? o Has the resident received a psychological or psychiatric evaluation to evaluate, diagnose, or treat her/his condition, if necessary? o Identify if resident triggers RAPs for activities, mood state, psychosocial well-being, and psychotropic drug use. Consider whether the RAPs were used to assess the causal factors for decline, potential for decline or lack of improvement. o How are mental and psychosocial adjustment difficulties addressed in the care plan? See §483.45(a), F406 for health rehabilitative services for mental illness and mental retardation.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F319 Cont.		psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.
F320	F320 (2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern is unavoidable.	Procedures: §483.25(f)(2) For sampled residents whose assessment did not reveal a mental or psychosocial adjustment difficulty, but who display decreased social interaction or increased withdrawn, angry, or depressed behaviors, determine, as appropriate, was this behavior unavoidable. Probes: §483.25(f)(2) o Did the facility attempt to evaluate whether this behavior was attributable to organic causes or other risk factors not associated with adjusting to living in the nursing facility? o What care did the resident receive to maintain his/her mental or psychosocial functioning? o Were individual objectives of the plan of care periodically evaluated, and if progress was not made in reducing, maintaining, or increasing behaviors that assist the resident to have his/her needs met, were alternative treatment approaches developed to maintain mental or psychosocial functioning? o Identify if resident triggers RAPs for behavior problem, cognitive loss/dementia, and psychosocial well-being. Consider whether the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement. o Did the facility use the RAPs for behavior problems, cognitive loss/dementia, and psychosocial well-being to assess why the behaviors or change in mental or psychosocial functioning was occurring?
F321	(g) Naso-gastric tubes. Based on the comprehensive assessment of a resident, the facility must ensure that-- (1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a	Intent: §483.25(g) The intent of this regulation is that a naso-gastric tube feeding is utilized only after adequate assessment, and the resident's clinical condition makes this treatment necessary. Guidelines: §483.25(g) This corresponds to MDS, section L; MDS 2.0 sections G, K, P when specified for use by the State. This requirement is also intended to prevent the use of tube feeding when ordered over the objection of the resident. Decisions about the appropriateness of tube feeding for a resident are developed with the resident or his/her family, surrogate or representative as part of determining the care plan.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F321 (Cont.)	naso-gastric tube was unavoidable; and	Complications in tube feeding are not necessarily the result of improper care, but assessment for the potential for complications and care and treatment are provided to prevent complications in tube feeding by the facility.
F322	(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.	Clinical conditions demonstrating that nourishment via an naso-gastric tube is unavoidable include: o The inability to swallow without choking or aspiration, i.e., in cases of Parkinson's disease, pseudobulbar palsy, or esophageal diverticulum; o Lack of sufficient alertness for oral nutrition (e.g., resident comatose); and o Malnutrition not attributable to a single cause or causes that can be isolated and reversed. There is documented evidence that the facility has not been able to maintain or improve the resident's nutritional status through oral intake. Probes: §483.25(g) For sampled residents who, upon admission to the facility, were not tube fed and now have a feeding tube, was tube feeding unavoidable? To determine if the tube feeding was unavoidable, assess the following: o Did the facility identify the resident at risk for malnutrition? o What did the facility do to maintain oral feeding, prior to inserting a feeding tube? Did staff provide enough assistance in eating? Did staff cue resident as needed, assist with the use of assistive devices, or feed the resident, if necessary? o Is the resident receiving therapy to improve or enhance swallowing skills, as need, is identified in the comprehensive assessment? o Was an assessment done to determine the cause of decreased oral intake/weight loss or malnutrition? o If there was a dietitian consultation, were recommendations followed? For all sampled residents who are tube fed: o Is the NG tube properly placed? o Are staff responsibilities for providing enteral feedings clearly assigned (i.e., who administers the feeding, formula, amount, feeding intervals, flow rate)? o Do staff monitor feeding complications (e.g., diarrhea, gastric distension, aspiration) and administer corrective actions to allay complications (e.g., changing rate of formula administration)? o Are there negative consequences of tube use (e.g., agitation, depression, self-extubation, infections, aspiration and restraint use without a medical reason for the restraint)? o When long term use is anticipated, is G tube placement considered? Is the potential for complications from feedings minimized by: o Use of a small bore, flexible naso-gastric tube, unless contraindicated; o Securely attached the tube to the nose/face;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F322 (Cont.)		o Checking for correct tube placement prior to beginning a feeding or administering medications and after episodes of vomiting or suctioning; o Checking a resident with a newly inserted gastric tube for gastric residual volume every 2-4 hours until the resident has demonstrated an ability to empty his/her stomach; o Properly elevating the resident's head; o Providing the type, rate and volume of the feeding as ordered; o Using universal precautions and clean technique and as per facility/manufacturer's directions when stopping, starting, flushing, and giving medications through the tube; o Using hang time recommendations by the manufacturer to prevent excessive microbial growth; o Implement the procedures to ensure cleanliness of supplies, e.g. irrigating syringes changed on a regular bases as per facility policy. It is not necessary to change the irrigating syringe each time it is used; o Using a pump equipped with a functional alarm (if pump used); o The facility's criteria for determining that a resident may be able to return to eating by mouth (e.g., a resident whose Parkinson's symptoms have been controlled); o There are sampled residents meet these criteria; o If so, the facility has assisted them in returning to normal eating; and o Identify if resident triggers RAPs for feeding tubes, nutritional status, and dehydration/fluid maintenance. Consider whether the RAPs were used to assess causal factors for decline, potential for decline and lack of improvement.
F323	(h) Accidents The facility must ensure that – (1) The resident environment remains as free of accident hazards as is possibled; and	Intent: §483.25(h)(1) The intent of this provision is that the facility prevents accidents by providing an environment that is free from hazards over which the facility has control. Guidelines: §483.25(h)(1) This corresponds to MDS, section K2, MDS version 2.0 section J, when specified for use by the State. "Accident hazards" are defined as physical features in the NF environment that can endanger a resident's safety, including but not limited to: o Physical restraints (see physical restraints §483.13); o Equipment or devices that are defective, poorly maintained, or not used in accordance with manufacturer's specifications (e.g., wheelchairs or geri-chairs with nonworking brakes, and loose nuts and bolts on walkers); o Bathing facilities that do not have nonslip surfaces; o Hazards (e.g., electrical appliances with frayed wires, cleaning supplies easily accessible to cognitively impaired residents, wet floors that are not obviously labeled and to which access is not blocked); o Defective or improperly latched side rails or spaces within side rails, between upper and lower rails, between rails and the mattress, between side rails and the bed frame, or spaces between side rails and the head or foot board of the bed that can entrap limbs, neck or thorax, and can cause injury or death;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F323 Cont.		o Handrails not securely fixed to the wall, difficult to grasp, and/or with sharp edges/splinters; and o Water temperatures in hand sinks or bath tubs which can scald or harm residents. Probes: §483.25(h)(1) (See F221 for guidance concerning the use of bedrails.) See also §483.70(h) - Safe Environment.
F324	(2) Each resident receives adequate supervision and assistance devices to prevent accidents.	Intent §483.25(h)(2) The intent of this provision is that the facility identifies each resident at risk for accidents and/or falls, and adequately plans care and implements procedures to prevent accidents. An "accident is an unexpected, unintended event that can cause a resident bodily injury. It does not include adverse outcomes associated as a direct consequence of treatment or care, (e.g., drug side effects or reactions). Procedures: §483.25(h)(2) o If a resident(s) selected for a comprehensive or focused review has had an accident, review the facility's investigation of that accident and their response to prevent the accident from recurring. o Identify if the resident triggers RAPs for falls, cognitive loss/dementia, physical restraints, and psychotropic drug use and whether the RAPs were used to assess causal factors for decline or lack of improvement. o If the survey team identifies a number of or pattern of accidents, in Phase II sampling, review the quality assurance activities of the facility to determine the facility's response to accidents. Probes: §483.25(h)(2): 1. Are there a number of accidents or injuries of a specific type or on any specific shift (e.g., falls, skin injuries)? 2. Are residents who smoke properly supervised and monitored? 3. If the survey team identifies residents repeatedly involved in accidents or sampled residents who have had an accident: a. Is the resident assessed for being at risk for falls? b. What care-planning and implementation is the facility doing to prevent accidents and falls for those residents identified at risk? c. How did the facility fit, and monitor, the use of that resident's assistive devices? d. How were drugs that may cause postural hypotension, dizziness, or visual changes monitored?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(i) Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident--	Intent §483.25(i) The intent of this regulation is to assure that the resident maintains acceptable parameters of nutritional status, taking into account the resident's clinical condition or other appropriate intervention, when there is a nutritional problem.
F325	(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and	Guidelines: §483.25(i) This corresponds to MDS, section L; MDS 2.0 sections G, I, J, K and L when specified for use by the State. Parameters of nutritional status which are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).
F326	(2) Receives a therapeutic diet when there is a nutritional problem	Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should be examined in light of the individual's former life style as well as the current diagnosis. Suggested parameters for evaluating significance of unplanned and undesired weight loss are: Interval — Significant Loss — Severe Loss 1 month — 5% — Greater than 5% 3 months — 7.5% — Greater than 7.5% 6 months — 10% — Greater than 10% The following formula determines percentage of loss: % of body weight loss = (usual weight - actual weight) / usual weight x 100 In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food? Suggested laboratory values are: Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion) Plasma Transferrin >60 yr.:180-380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F326 Cont		Hemoglobin Males: 14-17 g/dl Females: 12-15 g/dl Hematocrit Males: 41 - 53 Females: 36 - 46 Potassium 3.5 - 5.0 mEq/L Magnesium 1.3 - 2.0 mEg/L Some laboratories may have different "normals". Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values. NOTE: There is no requirement that facilities order the tests referenced above. Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting. Risk factors for malnutrition are: 1.Drug therapy that may contribute to nutritional deficiencies such as: a. Cardiac glycosides; b. Diuretics; c. Anti - inflammatory drugs; d. Antacids (antacid overuse); e. Laxatives (laxative overuse); f. Psychotropic drug overuse; g. Anticonvulsants; h. Antineoplastic drugs; i. Phenothiazines; j. Oral hypoglycemics; 2.Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations; 3.Depression or dementia; 4.Therapeutic or mechanically altered diet; 5.Lack of access to culturally acceptable foods; 6.Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and 7.Cancer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F326 Cont.		Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to: o Refusal to eat and refusal of other methods of nourishment; o Advanced disease (i.e., cancer, malabsorption syndrome); o Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns); o Radiation or chemotherapy; o Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism; o Gastrointestinal surgery; and o Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice. " Therapeutic diet " means a diet ordered by a physician as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet). Procedures: §483.25(i) Determine if residents selected for a comprehensive review or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed? Probes: §483.25(i) For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable: o Did the facility identify factors that put the resident at risk for\ malnutrition? o Identify if resident triggered RAPs for nutritional status, ADL functional/rehabilitation potential, feeding tubes, psychotropic drug use, and dehydration/fluid balance. Consider whether the RAPs were used to assess the causal factors for decline, potential for decline or lack of improvement. o What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)? o Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes? o Was this care provided consistently? o Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F327(j)	Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health	Intent: §483.25(j) The intent of this regulation is to assure that the resident receives sufficient amount of fluids based on individual needs to prevent dehydration. Guidelines: §483.25(j) This corresponds to MDS, section L; MDS 2.0 sections G, K, I, J and L when specified for use by the State. "Sufficient fluid" means the amount of fluid needed to prevent dehydration (output of fluids far exceeds fluid intake) and maintain health. The amount needed is specific for each resident, and fluctuates as the resident's condition fluctuates (e.g., increase fluids if resident has fever or diarrhea). Risk factors for the resident becoming dehydrated are: o Coma/decreased sensorium; o Fluid loss and increased fluid needs (e.g., diarrhea, fever, uncontrolled diabetes); o Fluid restriction secondary to renal dialysis; o Functional impairments that make it difficult to drink, reach fluids, or communicate fluid needs (e.g., aphasia); o Dementia in which resident forgets to drink or forgets how to drink; o Refusal of fluids; and o Did the MDS trigger RAPs on hydration? What action was taken based on the RAP? Consider whether assessment triggers RAPs and are RAPs used to assess the causal factors for decline, potential for decline or lack of improvement. A general guideline for determining baseline daily fluids needs is to multiply the resident's body weight in kg times 30cc (2.2 lbs = 1kg), except for residents with renal or cardiac distress. An excess of fluids can be detrimental for these residents. Procedures: §483.25(j) Identify if resident triggers RAPs for dehydration/fluid maintenance, and cognitive loss. Probes: §483.25(j) Do sampled residents show clinical signs of possible insufficient fluid intake (e.g., dry skin and mucous membranes, cracked lips, poor skin turgor, thirst, fever), abnormal laboratory values (e.g., elevated hemoglobin and hematocrit, potassium, chloride, sodium, albumin, transferrin, blood urea nitrogen (BUN), or urine specific gravity)? Has the facility provided residents with adequate fluid intake to maintain proper hydration and health? If not: o Did the facility identify any factors that put the resident at risk of Dehydration?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F327 Cont.		o What care did the facility provide to reduce those risk factors and ensure adequate fluid intake (e.g., keep fluids next to the resident at all times and assisting or cuing the resident to drink)? Is staff aware of need for maintaining adequate fluid intake? and o If adequate fluid intake is difficult to maintain, have alternative treatment approaches been developed, attempt to increase fluid intake by the use of popsicles, gelatin, and other similar non-liquid foods?
F328	(k) Special needs. The facility must ensure that residents receive proper treatment and care for the following special services:	Intent: 483.25(k) The intent of this provision is that the resident receives the necessary care and treatment including medical and nursing care and services when they need the specialized services as listed below. Guidelines: §483.25(k) This corresponds to MDS section P; MDS 2.0 section P when specified by for use by the State. The non-availability of program funding does not relieve a facility of its obligation to ensure that its residents receive all needed services listed in §1819(b)(4)(A) of the Act for Medicare and §1919(b)(4)(A) of the Act for Medicaid. For services not covered, a facility is required to assist the resident in securing any available resources to obtain the needed services.
	(1) Injections;	Probes: §483.25(k)(1) For sampled residents receiving one or more of these services within 7 days of the survey: o Is proper administration technique used (i.e., maintenance of sterility; correct needle size, route)? o Are there signs of redness, swelling, lesions from previous injections? o If appropriate, is resident observed for adverse reaction after the injection? o Are syringes and needles disposed of according to facility policy and accepted Practice (e.g., Centers for Disease Control and Prevention and Occupational Safety and Health Administration guidelines)? o Do nursing notes indicate, as appropriate, the resident's response to treatment (e.g., side effects/adverse actions; problems at the injection site(s); relief of pain)
	(2) Parenteral and enteral fluids	Probes: §483.25(k)(2) This corresponds to MDS, sections L4 and P1; MDS 2.0 sections L6 and P1 when specified for use by the State

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F328 Cont.		For residents selected for a comprehensive review, or focused review as appropriate, receiving one or more of these services within 7 days of the survey: o Are there signs of inflammation or infiltration at the insertion site? o If the IV site, tubing, or bottle/bag is changed, is sterile technique Maintained? o Is the rate of administration that which is ordered by the physician? Has the resident received the amount of fluid during the past 24 hours that he/she should have received according to the physician's orders (allow flexibility up to 150cc unless an exact fluid intake is critical for the resident)? Procedures: §483.25(k)(2) See §483.25(g) for enteral feedings (includes gastrostomy).
	3) Colostomy, ureterostomy, or ileostomy care;	Procedures: §483.25(k)(3) This corresponds to MDS 2.0 sections G, H and P when specified for use by the State. Identify if resident triggers RAPs for urinary incontinence, nutritional status, pressure ulcers (skin care). Probes: §483.25(k)(3) o If appropriate, is the resident provided with self-care instructions? Does the staff member observe and respond to any signs of resident's discomfort about the ostomy or its care? o Is skin surrounding the ostomy free of excoriation (abrasion, breakdown)? o If excoriation is present, does the clinical record indicate an onset and a plan of care to treat the excoriation?
	(4) Tracheostomy care	Procedures: §483.25(k)(4) (Includes care of the tracheostomy site) This corresponds to MDS, sections N and P; MDS 2.0 sections M and P when specified for use by the State. Observations for tracheostomy care are most appropriate for residents with new or relatively new tracheostomies, and may not be appropriate for those with tracheostomies of long standing. Probes: §483.25(k)(4) (Includes care of the tracheostomy site) o Is the skin around the tracheostomy clean and dry? Are the dressing and the ties clean and dry, with the cannula secure?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
328 Cont.		o Does the resident have signs of an obstructed airway or need for suctioning (e.g., secretions draining from mouth or tracheotomy; unable to cough to clear chest; audible crackles or wheezes; dyspneic, restless or agitated)? o If appropriate for a specific resident, is there a suction machine and catheter immediately available? o Is there an extra cannula of the correct size at the bedside or other place easily accessible if needed in an emergency? For sampled residents receiving one or more of these services within 7 days of the survey: o Is suction machine available for immediate use, clean, working, and available to a source of emergency power? o Is there an adequate supply of easily accessible suction catheters?
	(5) Tracheal suctioning;	Probes: §483.25(k)(5) This corresponds to MDS, section P; MDS 2.0 section P when specified for use by the State.
	(6) Respiratory care;	Procedures: §483.25(k)(6) This corresponds to MDS, section P; MDS 2.0 section P when specified for use by the State. Includes use of respirators/ventilators, oxygen, intermittent positive pressure breathing (IPPB) or other inhalation therapy, pulmonary care, humidifiers, and other methods to treat conditions of the respiratory tract. Identify if resident triggers RAPs for delirium and dehydration/fluid maintenance. Probes: §483.25(k)(6) For sampled residents receiving one or more of these services within 7 days of the survey: o If oxygen is in use, are precautions observed (e.g., no smoking signs; cylinders secured)? o If the survey team observes a treatment being administered, is the resident encouraged and instructed on how to assist in the treatment? o Is the staff following the facility's protocol and/or written procedures for ventilators (e.g., functioning alarms); frequency of staff monitoring; monitoring of resident response (e.g., use of accessory muscles to breathe, cleanliness of mouth, skin irritation), and availability of manual resuscitators? o If the resident is ventilator dependent, is routine machine maintenance and Care done (e.g., water changes/tubing changes, safety checks on alarms, and machine functioning checks)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
328 Cont.	(7) Foot care; and	Procedures: §483.25(k)(7) This corresponds with MDS, section M6; MDS 2.0 sections G and M when specified for use by the State. Includes treatment of foot disorders by qualified persons, e.g., podiatrist, Doctor of Medicine, Doctor of Osteopathy), including, but not limited, to corns, neuroma, calluses, bunions, heel spurs, nail disorders, preventive care, to avoid foot problems in diabetic residents and residents with circulatory disorders. Probes: §483.25(k)(7) For residents selected for a comprehensive review, or focused review, as appropriate: o Do nails, corns, calluses, and other foot problems appear unattended; do these foot problems interfere with resident mobility? o Are residents able to see a qualified person when they want? o What preventive foot care do staff provide diabetic residents?
	(8) Prostheses.	Probes: §483.25(k)(8) MDS 2.0 sections D, G, L, M and P when specified for use by the State. Includes artificial limbs, eyes, teeth. For residents selected for a comprehensive review, or focused review, as appropriate: o Is resident able to put on the prosthesis by himself/herself or with some assistance? o Are residents wearing their prostheses? o Does the prosthesis fit correctly? o Is skin/mucous membrane in contact with the prosthesis free of abrasions, wounds, irritation?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(l) Unnecessary drugs. (1) General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:	It is important to note that these regulations and interpretive guidelines are not meant to cast a negative light on the use of psychopharmacological drugs in long term care facilities. The use of psychopharmacological drugs can be therapeutic and enabling for residents suffering from mental illnesses such as schizophrenia or depression. The goal of these regulations and guidelines is to stimulate appropriate differential diagnosis of "behavioral symptoms" so the underlying cause of the symptoms is recognized and treated appropriately. This treatment may include the use of environmental and/or behavioral therapy, as well as, psychopharmacological drugs. The goal of these regulations is also to prevent the use of psychopharmacological drugs when the "behavioral symptom" is caused by conditions such as: (1) environmental stressors (e.g., excessive heat, noise, overcrowding, etc.); (2) psychosocial stressors (e.g., abuse, taunting, not following a resident's customary daily routine); or (3) treatable medical conditions (e.g., heart disease, diabetes, Chronic Obstructive Pulmonary Disease). Behavioral symptoms resulting from these causes should not be "covered up" with sedating drugs. An excellent differential diagnostic process for behavioral symptoms is described in the RAP on Behavior Problems (soon to be known as behavioral symptoms). Also, a number of very practical manuals are now available that teach nursing personnel how to assess and provide individualized care for behavioral symptoms, which leads to the avoidance of physical restraints, and unnecessary drugs. These manuals include, but are not limited to, the following list: 1. "Managing Behavior Problems in Nursing Home Residents" Department of Preventive Medicine Vanderbilt University School of Medicine 2. "Retrain, Don't Restrain" American Association of Homes and Services for the Aging, or The American Health Care Association 3. "Innovations in Restraint Reduction" American Health Care Association 4. "Avoiding Physical Restraint Use: New Standards in Care", and "Avoiding Drugs Used as Chemical Restraints: New Standards in Care" National Citizens' Coalition for Nursing Home Reform

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329	(i) in excessive dose (including duplicate therapy); or (ii) for excessive duration; or (iii) without adequate monitoring; or (iv) without adequate indications for its use; or (v) in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or (vi) any combinations of the reasons above.	Guidelines: §483.25(l)(l) A. Long-Acting Benzodiazepine Drugs The following long-acting benzodiazepine drugs should not be used in residents unless an attempt with a shorter-acting drug (i.e., those listed under B. Benzodiazepine or Other Anxiolytic/Sedative Drugs, and under C. Drugs Used for Sleep Induction) has failed. After an attempt with a shorter-acting benzodiazepine drug has failed, a long-acting benzodiazepine drug should not be used unless: o Evidence exists that other possible reasons for the resident's distress have been considered and ruled out. (See §483.25(l)(1)(iv);) o Its use results in maintenance or improvement in the resident's functional status (to evaluate functional status, see §483.25(a) through (k) and MDS, sections B through P; MDS 2.0 sections B through P). (See §483.25(l)(1)(iv);) o Daily use is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful (see §483.25(l)(1)(ii)); and o Its use is less than, or equal to, the following listed total daily doses unless higher doses (as evidenced by the resident's response and/or the resident's clinical record) are necessary for the maintenance, or improvement in the resident's functional status. (See §483.25(l)(1)(i).) LONG-ACTING BENZODIAZEPINES NOT MAXIMUM DOSES GENERIC / BRAND / DAILY ORAL DOSAGE Flurazepam (Dalmane) 15mg Chlordiazepoxide (Librium) 20mg Clorazepate (Tranxene) 15mg Diazepam (Valium) 5mg Clonazepam (Klonopin) 1.5mg Quazepam (Doral) 7.5mg Halazepam (Paxipam) 40mg NOTES: When diazepam is used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia or seizure disorders), this guideline does not apply. When long-acting benzodiazepine drugs are being used to withdraw residents from short-acting benzodiazepine drugs, this guideline does not apply.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		When clonazepam is used in bi-polar disorders, management of tardive dyskinesia, nocturnal myoclonus or seizure disorders, this guideline does not apply. The daily doses listed under long-acting Benzodiazepines are doses (usually administered in divided doses) for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it was necessary for the maintenance or improvement in the resident's functional status. "Duplicate drug therapy" is any drug therapy that duplicates a particular drug effect on the resident. For example, any two or more drugs, whether from the same drug category or not, which have a sedative effect. Duplicate drug therapy should prompt the facility to evaluate the resident for accumulation of the adverse effects. For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated. B. Benzodiazepine or other Anxiolytic/Sedative Drugs Use of listed Anxiolytic/Sedative drugs for purposes other than sleep induction should only occur when: 1. Evidence exists that other possible reasons for the resident's distress have been considered and ruled out. (See §483.25(l)(1)(iv);) 2. Use results in a maintenance or improvement in the resident's functional status, (to evaluate functional status, see §483.25(a) through (k) and MDS, sections B through P; MDS 2.0 sections B through P). (See §483.25(l)(1)(iv);) 3. Daily use (at any dose) is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful. (See §483.25(l)(1)(ii);) 4. Use is for one of the following indications as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or subsequent editions. (See §483.25(l)(1)(iv):) a. Generalized anxiety disorder; b. Organic mental syndromes (now called "delirium, dementia, and amnestic and other cognitive disorders" by DSM-IV) with associated agitated behaviors, which are quantitatively and objectively documented (see note number one) which are persistent and not due to preventable reasons and which constitute sources of distress or dysfunction to the resident or represent a danger to the resident or others;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		c. Panic disorder; d. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder (e.g., depression, adjustment disorder); and 5.o Use is equal to or less than the following listed total daily doses, unless higher doses (as evidenced by the resident response and/or the resident's clinical record) are necessary for the improvement or maintenance in the resident's functional status. (See §483.25(l)(1)(i), F342.)

SHORT-ACTING BENZODIAZEPINES NOT MAXIMUM DOSES

GENERIC	BRAND	DAILY ORAL DOSAGE
Lorazepam	(Ativan)	2 mg
Oxazepam	(Serax)	30mg
Alprazolam	(Xanax)	0.75mg
Estazolam	(ProSom)	0.5mg
OTHER ANXIOLYTIC AND SEDATIVE DRUGS		
Diphenhydramine	(Benadryl)	50mg
Hydroxyzine	(Atarax,Vistaril	50mg
Chloral Hydrate	(Many Brands)	750mg

NOTES: 1. This documentation is often referred to as "behavioral monitoring charts" and is necessary to assist in: (a) assessing whether the resident's behavioral symptom is in need of some form of intervention, (b) determining whether the behavioral symptom is transitory or permanent, (c) relating the behavioral symptom to other events in the resident's life in order to learn about potential causes (e.g., death in the family, not adhering to the resident's customary daily routine), (d) ruling out environmental causes such as excessive heat, noise, overcrowding, etc., (e) ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be know as behavioral symptoms).

2. The daily doses listed under Short-Acting Benzodiazepines are doses (usually administered in divided doses) for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and, when necessary, only gradually increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident's functional status.

3. For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that a gradual dose reduction is clinically contraindicated.

4. Diphenhydramine, hydroxyzine and chloral hydrate are not necessarily drugs of choice for treatment of anxiety disorders. They are only listed here in the event of their potential use.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		C. Drugs for Sleep Induction Drugs used for sleep induction should only be used if: o Evidence exists that other possible reasons for insomnia (e.g., depression, pain, noise, light, caffeine) have been ruled out. (See §483.25(l)(1)(iv)); o The use of a drug to induce sleep results in the maintenance or improvement of the resident's functional status (to evaluate functional status, see §483.25(a) through (k) and MDS, Sections B through P; MDS 2.0 sections B through P). (See §483.25(l)(1)(iv);) o Daily use of the drug is less than ten continuous days unless an attempt at a gradual dose reduction is unsuccessful. (See §483.25(l)(1)(ii);) and o The dose of the drug is equal or less than the following listed doses unless higher doses (as evidenced by the resident response and/or the resident's clinical record) are necessary for maintenance or improvement in the residents functional status. (See §483.25(l)(1)(i).) HYPNOTIC DRUGS NOT MAXIMUM DOSES GENERIC — BRAND — DOSE BY MOUTH Temazepam — (Restoril) — 7.5mg Triazolam — (Halcion) — 0.125mg Lorazepam — (Ativan) — 1mg Oxazepam — (Serax) — 15mg Alprazolam — (Xanax) — 0.25mg Estazolam — (ProSom) — 0.5mg Diphenhydramine — (Benadryl) — 25mg Hydroxyzine — (Atarax,Vistaril) — 50mg Chloral Hydrate — (Many Brands) — 500mg Zolpidem — (Ambien) — 5mg NOTES: 1. Diminished sleep in the elderly is not necessarily pathological. 2. The doses listed are doses for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident's functional status.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		3. Diphenhydramine, hydroxyzine, and chloral hydrate are not necessarily drugs of choice for sleep disorders. They are listed here only in the event of their potential use. 4. For drugs in this category, a gradual dose reduction should be attempted at least three times within six months before one can conclude that a gradual dose reduction is clinically contraindicated. D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs The initiation of the following hypnotic/sedative/anxiolytic drugs should not occur in any dose for any resident. (See Notes for exceptions.) Residents currently using these drugs or residents admitted to the facility while using these drugs should receive gradual dose reductions as part of a plan to eliminate or modify the symptoms for which they are prescribed. A gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated. Newly admitted residents using these drugs may have a period of adjustment before a gradual dose reduction is attempted. (CAUTION: DO NOT ENCOURAGE RAPID WITHDRAWAL OF THESE DRUGS. THIS MIGHT RESULT IN SEVERE PHYSIOLOGICAL WITHDRAWAL SYMPTOMS. BARBITURATES (EXAMPLES) GENERIC — BRAND Amobarbital — (Amytal) Butabarbital — (Butisol, others) Pentobarbital — (Nembutal) Secobarbital — (Seconal) Phenobarbitol — (Many Brands) Amobarbital-Secobarbital — (Tuinal) Barbiturates with other drugs — (e.g., Fiorinal)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		MISCELLANEOUS HYPNOTIC/SEDATIVE/ANXIOLYTICS GENERIC — BRAND Glutethimide (Doriden) Methprylon (Noludar) Ethchlorvynol (Placidyl) Meprobamate (Equinal, Miltown) Paraldehyde (Many brands) 1. Any sedative drug is expected from this Guideline when used as a single dose sedative for dental or medical procedures. 2. Phenobarbital is excepted from this Guideline when used in the treatment of seizure disorders. 3. When Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs are used outside these Guidelines they may be unnecessary drugs as a resul of inadequate indications for use. (See Survey Procedures and Probes.) E. ANTIPSYCHOTIC DRUG DOSAGE LEVELS The following examples of antipsychotic drugs should not be used in excess of the listed doses for residents with organic mental syndromes (now called "delirium, dementia, and amnestic and other cognitive disorders" by DSM-IV) unless higher doses (as evidenced by the resident's response or the resident's clinical record) are necessary to maintain or improve the resident's functional status. To evaluate functional status, see §§483.25(a) through (k) and MDS, sections B through P; MDS 2.0 sections B through P. **SCREEN FOR HIGHER DOSES OF ANTIPSYCHOTIC DRUGS** These dose levels are **NOT MAXIMUM DOSES.** These daily dose levels are given to establish a point at which higher doses should be explained. If a resident is prescribed a higher dose than shown, the facility should explain the specific clinical circumstance requiring the higher dose.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		ANTIPSYCHOTIC DRUGS

GENERIC	BRAND	DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Chlorpromazine	(Thorazine)	75
Promazine	(Sparine)	150
Trifluprom azine	(Vesprin)	20
Thioridazine	(Mellaril)	75
Mesoridazine	(Serentil)	25
Acetophenazine	(Tindal)	20
Perphenazine	(Trilafon)	8
Fluphenazine	(Prolixin, Permitil)	4
Trifluoperazine	(Stelazine)	8
Chlorprothixene	(Taractan)	75
Thiothixene	(Navane)	7
Haloperidol	(Haldol)	4
Molindone	(Moban)	10
Loxapine	(Loxitane)	10
Clozapine	(Clozaril)	50
Prochlorperazine	(Compazine)	10
Risperidone	(Risperdal)	2
Olanzapine	(Zyprexa)	10
Quetiapine	(Seroquel)	200

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		1. The doses listed are daily doses (usually administered in divided doses) for residents with organic mental syndromes (now called "Delirium, Dementia, and Amnestic and other cognitive disorders by DSM-IV). The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it is necessary for the maintenance or improvement in the resident's functional status. 2. The "specific conditions" for use of antipsychotic drugs are listed under the Guideline for "483.25(l)(1) and (2). 3. The dose of prochlorperazine may be exceeded for short term (seven day) treatment of nausea and vomiting. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can also be treated with higher doses for longer periods of time. 4. When antipsychotic drugs are used outside these Guidelines without valid reasons for the higher dose, they may be deemed unnecessary drugs as a result of excessive dose. F. Monitoring for Antipsychotic Drug Side Effects The facility assures that residents who are undergoing antipsychotic drug therapy receive adequate monitoring for significant side effects of such therapy with emphasis on the following: o Tardive dyskinesia; o Postural (orthostatic) hypotension; o Cognitive/behavior impairment; o Akathisia; and o Parkinsonism. NOTES: For a more detailed description of these side effects, see the RAP: Psychotropic Drug Use, pg. F-72, Resident Assessment Instrument Training Manual and Resource Guide, 1990 edition.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		When antipsychotic drugs are used without monitoring for these side effects, they may be unnecessary drugs because of inadequate monitoring. G. Antidepressant Drugs The under diagnosis and under treatment of depression in nursing homes has been documented in a Journal of the American Medical Association paper entitled "Depression and Mortality in the Nursing Home" (JAMA, February 27, l991-vol. 265, No. 8). HCFA continues to support the accurate identification and treatment of depression in nursing homes. The following is a list of commonly used antidepressant drugs: Antidepressant Drugs Generic Name — Brand Name Amitriptyline* (Elavil) Amoxapine (Asendin) Desipramine (Norpramin, Pertofrane) Doxepin* (Sinequan) Imipramine* (Tofranil) Maprotiline (Ludiomil) Nortriptyline (Aventyl, Pamelor) Protriptyline (Vivactil) Trimipramine* (Surmontil) Fluoxetine (Prozac) Sertraline (Zoloft)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		Antidepressant Drugs (Cont.) Generic Name — Brand Name Trazodone (Desyrel) Clomipramine* (Anafranil) Paroxetine (Paxil) Bupropion (Wellbutrin) Isocarboxazid* (Marplan) Phenelzine* (Nardil) Tranylcypromine* (Parnate) Venlafaxine (Effexor) Nefazodone (Serzone) Fluvoxamine (Luvox) * These are not necessarily drugs of choice for depression in the elderly. They are listed here only in the event of their potential use. Procedures: 483.25(l)(1) Consider drug therapy "unnecessary" only after determining that the facility's use of the drug is: o In excessive dose (including duplicate drug therapy); o For excessive duration; o Without adequate monitoring; o Without adequate indications of use; o In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or o Any combination of the reasons above. Allow the facility the opportunity to provide a rationale for the use of drugs prescribed outside the preceding Guidelines. The facility may not justify the use of a drug prescribed outside the proceeding Guidelines solely on the basis of "the doctor ordered it." This justification would render the regulation meaningless. The rationale must be based on sound risk-benefit analysis of the resident's symptoms and potential adverse effects of the drug.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		Examples of evidence that would support a justification of why a drug is being used outside these Guidelines but in the best interests of the resident may include, but are not limited to: o A physician's note indicating for example, that the dosage, duration, indication, and monitoring are clinically appropriate, and the reasons why they are clinically appropriate; this note should demonstrate that the physician has carefully considered the risk/benefit to the resident in using drugs outside the Guidelines. o A medical or psychiatric consultation or evaluation (e.g., Geriatric Depression Scale) that confirms the physician's judgment that use of a drug outside the Guidelines is in the best interest of the resident. o Physician, nursing, or other health professional documentation indicating that the resident is being monitored for adverse consequences or complications of the drug therapy; o Documentation confirming that previous attempts at dosage reduction have been unsuccessful; o Documentation (including MDS documentation) showing resident's subjective or objective improvement, or maintenance of function while taking the medication; o Documentation showing that a resident's decline or deterioration is evaluated by the interdisciplinary team to determine whether a particular drug, or a particular dose, or duration of therapy, may be the cause; o Documentation showing why the resident's age, weight, or other factors would require a unique drug dose or drug duration, indication, monitoring; and o Other evidence the survey team may deem appropriate. If the survey team determines that there is a deficiency in the use of antipsychotics, cite the facility under either the "unnecessary drug" regulation or the "antipsychotic drug" regulation, but not both. NOTE: The unnecessary drug criterion of "adequate indications for use" does not simply mean that the physician's order must include a reason for using the drug (although such order writing is encouraged). It means that the resident lacks a valid clinical reason for use of the drug as evidenced by the survey team's evaluation of some, but not necessarily all, of the following: resident assessment, plan of care, reports of significant change, progress notes, laboratory reports, professional consults, drug orders, observation and interview of the resident, and other information.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		H. Miscellaneous Drugs that are Potentially Inappropriate in the Elderly: The following list of drugs and diagnoses/drug combinations have been partially adapted from a paper entitled "Explicit Criteria for Determining Inappropriate Medication Use by the Elderly" by Mark H. Beers, MD. This paper was published in the *Archives of Internal Medicine,* Vol. 157, July 28, 1997. The paper lists numerous drugs and diagnosis/drug combinations that are judged to place a person over the age of 65 at greater risk of adverse drug outcomes (ADR). The judgments in this paper were arrived at through an extensive review of the literature by a panel of experts. There are two important quotations from the paper that the surveyor should keep in mind at all times: 1. "These criteria were developed to predict when the potential for adverse outcomes is greater than the potential for benefit"; and 2. "Without measuring outcomes, criteria cannot determine whether adverse outcomes have occurred; they can only determine that they are more likely to occur." These criteria are divided into two broad categories. Drug therapy that is classified as having "high severity" and therapy that is considered as not having "high severity." Severity is defined as: "a combination of both the likelihood that an adverse outcome would occur and the clinical significance of that outcome should it occur." The survey guidelines are ocated in two parts, F329 and F429. The surveyor has the option to cite at either or both tags depending on the situation. 1. Drug Therapy With High Potential for Severe Adverse Outcomes in Persons Over 65 that are to be used to determine compliance with 483.25(l)(1), Unnecessary Drug (F329); and 2. Drug Therapy With High Potential for Less Severe Adverse Outcomes In Persons Over 65 that are to be used to determine compliance with 483.60(c)(1), Drug Regimen Review Report (F429) which are located under guidance to surveyors for drug regimen review. It should be noted that medication alterations may not be appropriate for some short-term residents. Many residents arrive in the long term care setting already on medications that they have managed to tolerate for years or that have been prescribed in the hospital. For some short-stay residents, it is difficult to change these medications without a period of observation and information gathering. Therefore, review by the surveyor is not necessary for drug therapy given the first seven consecutive days upon admission/readmission, unless there is an immediate threat to health and safety. These guidelines do not supercede the unnecessary drug guidelines and drug regimen review guidelines.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		LIST OF DRUGS WITH HIGH POTENTIAL FOR SEVERE ADVERSE OUTCOMES 1. Pentazocine (Talwin) Risk: **"Pentazocine is a narcotic analgesic that causes more central nervous system side effects, including confusion and hallucinations, more commonly than other narcotic drugs."** Dizziness, lightheadedness, euphoria, and sedation are also common side effects of pentazocine. 2. Long-Acting Benzodiazepines NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329) already has guidelines for Long Acting Benzodiazepine Drugs. The Surveyor should use that guideline. This guideline is repeated here to give emphasis to potential side effects of these drugs. Risk: "**These benzodiazepine drugs have an extremely long half-life in the elderly (often days), producing prolonged sedation and increased incidence of falls and fractures."** Other common side effects of benzodiazepine drugs include drowsiness, ataxia, fatigue, confusion, weakness, dizziness, vertigo, syncope, and psychological changes. 3. Amitriptyline (Elavil) Also include combination products such as: Amitriptyline and chlordiazepoxide (Limbitrol) Amitriptyline and Perphenazine (Triavil). Risk: "**Because of its strong anticholinergic and sedating properties, amitriptyline is rarely the antidepressant of choice in the elderly."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. Amitriptyline can also cause cardiac arrhythmias and orthostatic hypotension. Exception: Surveyor review is not required if: o The resident is being treated for neurogenic pain (that is trigeminal neuralgia, peripheral neuropathy); o There is evidence in the record that the resident has experienced this type of pain; and o That a risk/benefit has been considered, including alternative pain therapies that may have fewer side effects in the individual.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		4. Doxepin (Sinequan) Risk: "**Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice in the elderly."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. Doxepin may also cause cardiac arrhythmias. 5. Meprobamate (Miltown), (Equanil) NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329)) already has guidelines for this drug under "D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs." This guideline is provided here to further emphasize the risk of using this drug. Risk: "M**eprobamate is a highly addictive and sedating anxiolytic (i.e., antianxiety drug). Avoid in elderly patients. Those using memprobamate for prolonged periods may be addicted and may need to be withdrawn slowly."** The most frequent side effects of meprobamate are drowsiness and ataxia. 6. Disopyramide (Norpace), (Norpace CR) Risk: "D**isopyramide, of all antiarrhythmic drugs, is the most potent negative inotrope (decreased force of heart contraction) and therefore may induce heart failure in the elderly. It is also strongly anticholinergic."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. In addition to the anticholinergic side effects, disopyramide has the following cardiovascular side effects: edema, weight gain, chest pain, dyspnea, syncope and hypotension. 7. Digoxin (Lanoxin) Risk: **Because of decreased renal clearance of digoxin, doses in the elderly should rarely exceed 0.125 mg daily, except when treating atrial arrhythmias.** (NOTE: the panelists' review of the literature has revealed countless studies showing that low dose digoxin is effective, but higher dose digoxin adds risks without improving outcomes.) Side effects may include anorexia, nausea and vomiting are the common early signs of digoxin toxicity. Nervous system symptoms include headache, fatigue, malaise, drowsiness, depression, and generalized muscle weakness. Visual disturbances also occur, including blurred vision, yellow or green vision, diplopia, photophobia, and flashing lights.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		High Severity: **Yes, if recently started.** The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month, it should be treated as a High Potential for Less Severe Outcomes under F429. It should be noted that validating when the drug was started is often a complex issue, and may be too much of a burden for the facility to accurately determine. If there is a diagnosis of an atrial arrhythmia, (e.g., atrial flutter, atrial fibrillation, supraventricular tachycardia), the survey must view the higher dose as acceptable. Exception: Higher doses may be used for up to seven days before the facility would have to justify the risk versus benefit in writing. The surveyor need not review the higher dose during the seven day period unless an immediate threat to health and safety, for example, digoxin toxicity, is suspected. 8. Methyldopa (Aldomet) Also combination products such as: Methyldopa and hydrochlorothiazide (Aldoril). Risk: **"Methyldopa may cause bradycardia and exacerbate depression in the elderly. Alternate treatments for hypertension are generally preferred."** **High Severity: Yes if recently started.** The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month it should be treated as a High Potential for Less Severe Outcomes under F429. It should be noted that validating when the drug was started is often a complex issue, and may be too much of a burden for the facility to accurately determine.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		9. Chlorpropamide (Diabinese) Risk: **"Chlorpropamide has a prolonged half-life in the elderly and can cause prolonged and serious hypoglycemia.** Hypoglycemic symptoms are as follows: Hypoglycemic Symptoms: Weakness, sweating, tachycardia, palpitations, tremor, nervousness, irritability, tingling in the mouth and tongue, hunger, nausea (unusual) and vomiting (unusual), headache, hypothermia, visual disturbances, mental dullness, confusion, amnesia, seizures, coma. Additionally, chlorpropamide is the only hypoglycemic agent that causes SIADH (syndrome of inappropriate antidiuretic hormone release). SIADH causes hyponatremia. Chlorpropamide should be avoided in the elderly. 10. Gastrointestinal antispasmodic drugs such as: Dicyclomine (Bentyl), Hyoscyamine (Levsin, Levsinex), Propantheline (Probanthine), Belladonna Alkaloids (Donnatal & others), Clidinium and chlordiazepoxide (Librax). Risk: **"Gastrointestinal antispasmodic drugs are highly anticholinergic and generally produce substantial toxic effects in the elderly. Additionally, their effectiveness at doses tolerated by the elderly is questionable. All these drugs are best avoided in the elderly, especially for long term use."** Anticholinergic side effects can include symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short period (not over seven days) for symptoms of an acute, self-limiting illness. 11. Barbiturates: NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329) already has guidelines for these drugs under: D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs. This guideline is provided here to further emphasize the risk of using these drugs.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		Risk: **"Barbiturates cause more side effects than most other sedative or hypnotic drugs in the elderly and are highly addictive. They should not be started as new therapy in the elderly except when used to control seizures."** Common side effects from barbiturates include: drowsiness, lethargy, vertigo, headache, severe CNS depression, mental depression, nausea, vomiting, diarrhea, and constipation. When discontinued, these drugs must be tapered very slowly to avoid potentially life-threatening withdrawal effects. 12. Meperidine (Demerol) Risk: **"Meperidine is not an effective analgesic when administered orally, and has many disadvantages to other narcotic drugs. Avoid oral use in the elderly."** Respiratory depression and, to a lesser degree, circulatory depression (including orthostatic hypotension) are the chief hazards of opiate agonists (e.g., meperidine). Respiratory arrest, shock, and cardiac arrest have occurred. Respiratory depression is produced even with therapeutic analgesic doses of opiate agonists (e.g., meperdine), but it is usually not clinically important in patients with normal respiratory function. **High Severity: Yes if recently started.** The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month it should be treated as a High Potential for Less Severe Outcomes under F429. 13. Ticlopidine (Ticlid) Risk: **"Ticlopidine has been shown to be no better than aspirin in preventing clotting and is considerably more toxic. Avoid in the elderly."** The most serious side effects of Ticlopidine involve the hematologic system, principally neutropenia, which may be life-threatening. The most common side effects of Ticlid which resulted in discontinuance of the drug were nausea, vomiting, diarrhea, GI pain, rash, and neutropenia. Exception: Review by the surveyor is not necessary in individuals who receive ticlopidine because they have had a previous stroke or have evidence of stroke precursors, that is, transient ischemic attacks (TIAs), and cannot tolerate aspirin.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		LIST OF DIAGNOSIS/DRUG COMBINATIONS WITH HIGH POTENTIAL FOR SEVERE ADVERSE OUTCOMES 1. Chronic Obstructive Pulmonary Disease (COPD) Drugs(s): Hypnotic/sedatives such as: - Long-Acting Benzodiazepines such as Flurazepam (Dalmane), Chlordiazepoxide (Librium), Clorazepate (Tranxene), Diazepam (Valium), Clonazepame (Klonopin), Quazepam (Doral), and Halazepam (Paxipam). - Barbiturates such as Amobarbital (Amytal), Butabarbital (Butisol), Pentobarbital (Nembutal), and Secobarbital (Seconal). - Miscellaneous Hypnotic/sedatives such as Glutethimide (Doriden), Methprylon (Noludar), Ethchlorvynol (Placidyl), Meprobamate (Equinal, Miltown), Paraldehyde (many brands), and Chloral Hydrate (Noctec). Risk: **"May slow respirations and increase carbon dioxide retention in persons with chronic obstructive pulmonary disease (COPD)."** NOTE: After review of the literature, the Panelists, in consultation with pulmonologists, determined, despite common usage of hypnotic/sedative drug use in persons with COPD, there is no data to support this practice, and pulmonologists virtually all agree that such drugs should be avoided in COPD patients for the reasons mentioned above. Potential Side Effects: Exacerbation of COPD symptoms. The most common symptoms of COPD are cough, increased sputum production, shortness of breath, tightness in the chest, burning sensation, and wheezing.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		Exception: The use of Short Acting Benzodiazepines such as Lorazapam (Ativan), Oxazepam (Serax) Alprazolam (Xanax) to relieve anxiety, preferably on an as needed basis, after thorough assessment and optimal treatment of the symptoms of COPD. 2. Active or recurrent gastritis, peptic ulcer disease or gastroesophageal reflux disease (GERD). Drugs: Non-Steroidal Anti-inflammatory Drugs (NSAIDs) such as Diclofenac (Cataflam & Voltaren), Diflunisal (Dolobid), Etodolac (Lodine), Fenoprofen (Nalfon), Ibuprofen (Motrin & Advil), Indomethacin (Indocin), Ketoprofen (Orudis), Nabumetone (Relafen), Naproxen (Anaprox), Oxaprozin (Daypro), Phenylbutazone (many brands), Piroxicam (Feldene), Sulindac (Clinoril), Tolmetin (Tolectin). Risk: **"May exacerbate ulcer disease, gastritis, and gastroesophageal reflux disease (GERD)."** Potential Side Effects: Nausea, Dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, and flatulence. 3. Seizures or epilepsy. Drug: Metoclopramide (Reglan). Risk: **May Lower seizure threshold.** 4. Blood Clotting Disorders. Drugs: Aspirin, NSAIDs (see #2 above for list), Dipyridamole (Persantine) and Ticlopidine (Ticlid). Risk: **"May cause bleeding in those using anticoagulants."** Potential Side Effects: Bleeding (e.g., from gums while brushing teeth or from small abrasions or contusions), and GI bleeding, indicated by black tarry stools, occult blood in the stool, or coffee ground like vomitus. A low hematocrit could be a sign of internal bleeding.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		5. Benign Prostatic Hypertrophy (BPH) Drugs: o Anticholinergic antihistamines such as Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril and Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripelanamine (PBZ), Dexchlorpheniramine (Polaramine); Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. o Anti-Parkinson medications such as Benztropine (Cogentin), Trihexyphenidyl (Artane), Procyclidine (Kemardren), Biperiden (Akineton); o GI antispasmodics such as dicyclomine (Bentyl) Hyoscyamine (Levsin & Levsinex), Propantheline (Probanthine), belladonna alkaloids (Donnatal), Clidinium containing products such as Librax; Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. o Anticholinergic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil). Risk: **"Anticholinergic drugs may impair micturition and cause obstruction in persons with Benign Prostatics Hypertrophy (BPH)."** Potential Side Effects: Urinary retention, urinary incontinence, reflux, pyelonephritis, nephritis, low grade temperature, and low back pain. 6. Arrhythmias Drugs: Tricyclic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		Risk: **"May induce arrhythmias."** Potential Side Effects: Cardiac arrhythmias. High Severity: **YES, if recently started.** The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month, it should be treated as a high potential for less severe outcomes drug under F429.
	(2) Antipsychotic drugs Based on a comprehensive assessment of a resident, the facility must assure that--	Guidelines: §483.25(1)(2)(i) For a list of examples of commonly used antipsychotic drugs, see E. Under Interpretive Guideline for §483.25(l)(1), Unnecessary Drug.

Next Page is PP-125

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F330	(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and	Antipsychotic drugs should not be used unless the clinical record documents that the resident has one or more of the following "specific conditions": 1. Schizophrenia; 2. Schizo-affective disorder; 3. Delusional disorder; 4. Psychotic mood disorders (including mania and depression with psychotic features); 5. Acute psychotic episodes; 6. Brief reactive psychosis; 7. Schizophreniform disorder; 8. Atypical psychosis; 9. Tourette's disorder; 10. Huntington's disease; 11. Organic mental syndromes (now called delirium, dementia, and amnestic and other cognitive disorders by DSM-IV) with associated psychotic and/or agitated behaviors: a. Which have been quantitatively and objectively documented. This documentation is necessary to assist in: (1) assessing whether the resident's behavioral symptom is in need of some form of intervention, (2) determining whether the behavioral symptom is transitory or permanent, (3) relating the behavioral symptom to other events in the resident's life in order to learn about potential causes (e.g., death in the family, not adhering to the resident's customary daily routine), (4) ruling out environmental causes such as excessive heat, noise, overcrowding, (5) ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be known as behavioral symptoms); and b. Which are persistent, and c. Which are not caused by preventable reasons; and d. Which are causing the resident to: (1) Present a danger to himself/herself or to others, or (2) Continuously scream, yell, or pace if these specific behaviors cause an impairment in functional capacity (to evaluate functional capacity, see §483.25 (a) through (k) and MDS sections B through P; MDS 2.0 sections B through P), or

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F330 Cont.		(3) Experience psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as dangerous behaviors or as screaming, yelling, or pacing but which cause the resident distress or impairment in functional capacity; or 12. Short-term (7 days) symptomatic treatment of hiccups, nausea, vomiting or pruritus. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can be treated for longer periods of time. Antipsychotics should not be used if one or more of the following is/are the <u>only</u> indication: o Wandering, o Poor self care, o Restlessness, o Impaired memory, o Anxiety, o Depression (without psychotic features), o Insomnia, o Unsociability, o Indifference to surroundings, o Fidgeting, o Nervousness, o Uncooperativeness, or o Agitated behaviors which <u>do not</u> represent danger to the resident or others.
F331	(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.	<u>Guidelines: §483.25(l)(2)(ii)</u> Residents must, unless clinically contraindicated, have gradual dose reductions of the antipsychotic drug. The gradual does reduction should be under close supervision. If the gradual dose reduction is causing an adverse effect on the resident and the gradual dose reduction is discontinued, documentation of this decision and the reasons for it should be included in the clinical record. Gradual dose reductions consist of tapering the resident's daily dose to determine if the resident's symptoms can be controlled by a lower dose or to determine if the dose can be eliminated altogether. "Behavioral interventions" means modification of the resident's behavior or the resident's environment, including staff approaches to care, to the largest degree possible to accommodate the resident's behavioral symptoms.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F331 Cont.		"Clinically contraindicated" means that a resident NEED NOT UNDERGO a "gradual dose reduction" or "behavioral interventions" IF: 1. The resident has a "specific condition" (as listed under one through ten on page P-185) and has a history of recurrence of psychotic symptoms (e.g., delusions, hallucinations), which have been stabilized with a maintenance dose of an antipsychotic drug without incurring significant side effects; 2. The resident has organic mental syndrome (now called--"Delirium, Dementia, and Amnestic and other Cognitive Disorders" by DSM IV) and has had a gradual dose reduction attempted TWICE in one year and that attempt resulted in the return of symptoms for which the drug was prescribed to a degree that a cessation in the gradual dose reduction, or a return to previous dose reduction was necessary; or 3. The resident's physician provides a justification why the continued use of the drug and the dose of the drug is clinically appropriate. This justification should include: (s) a diagnosis, but not simply a diagnostic label or code, but the description of symptoms, (b) a discussion of the differential psychiatric and medical diagnosis (e.g., why the resident's behavioral symptom is thought to be a result of a dementia with associated psychosis and/or agitated behaviors, and not the result of an unrecognized painful medical condition of a psychosocial or environmental stressor), (c) a description of the justification for the choice of a particular treatment, or treatments, and (d) a discussion of why the present dose is necessary to manage the symptoms of the resident. This information need not necessarily be in the physician's progress notes, but must be a part of the resident's clinical record. Procedures: §483.25(l)(2)(i) and (ii) In determining whether an antipsychotic drug is without a specific condition or that gradual dose reduction and behavioral interventions have not been performed, allow the facility an opportunity to justify why using the drug outside the Guidelines is in the best interest of the resident.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F331 (Cont.)		Examples of evidence that would support a justification of why a drug is being used outside the Guidelines, but in the best interest of the resident, may include, but are not limited to: o A physician's note indicating that the use of the drug, or continued use of the drug is clinically appropriate, and the reasons why this use is clinically appropriate. This note must demonstrate that the physician has carefully considered the risk/benefit to the resident in using drugs outside these Guidelines. o A medical or psychiatric consultation or evaluation (e.g., Geriatric Depression Scale) that confirms the physician's judgment that use of a drug outside the Guidelines is in the best interest of the resident. o Physician, nursing, or other health professional documentation indicating that the resident is being monitored for adverse consequences or complications of the drug therapy. o Documentation confirming that previous attempts at dosage reduction have been unsuccessful. o Documentation (including MDS documentation) showing resident's subjective or objective improvement or maintenance of function while taking the medication. o Documentation showing that a resident's decline or deterioration is evaluated by the interdisciplinary team to determine whether a particular drug, or a particular dose, or duration of therapy, may be the cause. o Documentation showing why the resident's age, weight, or other factors would require a unique drug dose or drug duration. o Other evidence the surveyor may deem appropriate.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F331 Cont.		The facility can refer to a prescriber's (or appropriately trained health professional's) justification as a valid justification for the use of a drug. It may not justify the use of a drug, its dose, its duration, solely on the basis that "it was ordered" without supportive information. If the survey team determines that there is a deficiency in the use of antipsychotics, cite the facility under either the unnecessary drug regulation or the antipsychotic drug regulation, but not both quality of care tags.
F332 F333	(m) Medication Errors. The facility must ensure that-- (1) It is free of medication error rates of five percent or greater; and (2) Residents are free of any significant medication errors.	Guidelines: §483.25(m) Medication Error--The observed preparation or administration of drugs or biologicals which is not in accordance with: (1) Physician's orders; (2) Manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological; (3) Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils. "Significant medication error" means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or relative term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a drug error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident's health and safety.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		"Medication error rate" is determined by calculating the percentage of errors. The numerator in the ratio is the total number of errors that the survey team observes, both significant and nonsignificant. The denominator is called "opportunities for errors" and includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows: Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100. "Medication error rate" --A medication error rate of 5% or greater includes both significant and nonsignificant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written. The error rate must be 5% or greater. Rounding of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. Significant and Nonsignificant Medication Errors "Determining Significance".--The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not: o Resident Condition.--The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant. o Drug Category.--If the drug is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI) (i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs with NTI are as follows: Anticonvulsant: phenytoin (Dilantin),carbamazepine (Tegretol), Anticoagulants: warfarin (Coumadin) Antiarrhythmic (digoxin)Lanoxin) Antiasthmatics: theophylline (TheoDur) Antimanic Drigs: lithium salts (Eskalith, Lithobid).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		o Frequency of Error.--If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's drug was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the drug category. Examples of Significant and Non-Significant Medication Errors.--Some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as nonsignificant have also been designated primarily on the basis of the nature of the drug. Resident status and frequency of error could classify these errors as significant. **Examples of Medication Errors Detected** Omissions **Examples** (Drug ordered but not administered at least once): DRUG ORDER — SIGNIFICANCE Haldol 1mg BID — NS* Motrin 400mg TID — NS Quinidine 200mg TID — S** Tearisol Drops 2 both eyes TID — NS Metamucil one packet BID — NS Multivitamin one daily — NS Mylanta Susp. one oz., TID AC — NS Nitrol Oint. one inch — S * Not Significant **Significant

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont.)		Unauthorized Drug **Examples** (Drugs administered without a physician's order):

DRUG ORDER	SIGNIFICANCE
Feosol	NS
Coumadin 4mg	S
Zyloprim 100mg	NS
Tylenol 5 gr	NS
Motrin 400mg	NS

Wrong Dose **Examples**:

DRUG ORDER	ADMINISTERED	SIGNIFICANCE
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Digoxin 0.125mg everyday	0.25mg	S
Amphojel 30cc QID	15cc	NS
Dilantin 125 SUSP	2cc 12cc	S

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		Wrong Route of Administration **Examples**: DRUG ORDER — ADMINISTERED — SIGNIFICANCE Cortisporin Ear Drops 4 to 5 left ear QID — Left Eye — S Wrong Dosage Form **Examples**: DRUG ORDER — ADMINISTERED — SIGNIFICANCE Colace Liquid 100mg BID — Capsule — NS Mellaril Tab 10mg — Liquid Concentrate — NS* Dilantin Kapseals 100 mg three Kapseals p.o. HS — Prompt Phenytoin 100 mg three capsules p.o. HS — S** * If correct dose was given. ** Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not. Wrong Drug **Examples**: DRUG ORDER — ADMINISTERED — SIGNIFICANCE Tums — Oscal — NS Vibramycin — Vancomycin — S

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		Wrong Time **Examples**: DRUG ORDER — ADMINISTERED — SIGNIFICANCE Digoxin 0.25mg daily at 8 a.m. — At 9:30 am — NS Percocet 2 Tabs 20 min. before painful treatment — 2 Tabs given 3 hrs after treatment — S Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards The following situations in drug administration may be considered medication errors: o Failure to "Shake Well": The failure to "shake" a drug product that is labeled "shake well." This may lead to an under dose or over dose depending on the drug product and the elapsed time since the last "shake." The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some drugs, for example dilantin, are more critical to achieve correct dosage delivery than others. o Insulin Suspensions: Also included under this category is the failure to "mix" the suspension without creating air bubbles. Some individuals "roll" the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration. o Crushing Medications that should not be Crushed: Crushing tablets or capsules that the manufacturer states "do not crush." Exceptions to the "Do Not Crush" rule:

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		- If the prescriber orders a drug to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects. - If the facility can provide literature from the drug manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care. o Adequate Fluids with Medications: The administration of medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication. For example: - Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel); - Nonsteroidal Anti-Inflammatory Drugs (NSAID's) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces. The surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes). If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted; and - Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted. o Medications that Must be Taken with Food or Antacids: The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used drugs that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAID's). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont.)		Examples of commonly used NSAID's are as follows: GENERIC NAME — BRAND NAME Diclofenac — Voltaren, Cataflam Diflunisal — Dolobid Etodolac — Lodine Fenoprofen — Nalfon Ibuprofen — Motrin, Advil Indomethacin — Indocin Ketoprofen — Orudis, Oruvail Mefenamic Acid — Ponstel Nabumetone — Relafen Naproxen — Naprosyn, Aleve Piroxicam — Feldene Sulindac — Clinoril Tolmetin — Tolectin Medications Administered with Enteral Nutritional Formulas: Administering medications immediately before, immediately after, or during the administration of enteral nutritional formulas (ENF's) without achieving the following minimum objectives: - Check the placement of the nasogastric or gastrostomy tube in accordance with the facility's policy on this subject. NOTE: If the placement of the tube is not checked, this is not a medication error; it is a failure to follow accepted professional practice and should be evaluated under F Tag 281 requiring the facility to meet professional standards of quality. - Flush the enteral feeding tube with at least 30 ml of preferably warm water before and after medications are administered. While it is noted that some facility policies ideally adopt flushing the tube after each individual medication is given, as opposed to after the group of multiple medications is given, unless there are known compatibility problems between medicines being mixed together, a minimum of one flushing before and after giving the medications is all the surveyor need review. There may be cases where flushing with 30 ml after each single medication is given may overload an individual with fluid, raising the risk of discomfort or stress on body functions. Failure to flush, before and after, would be counted as one medication error and would be included in the calculation for medication errors exceeding 5 percent.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont.)		- The administration of enteral nutrition formula and administration of dilantin should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of dilantin, then the surveyor should consider simultaneous administration a medication error. o Medications Instilled into the Eye: The administration of eye drops without achieving the following critical objectives: - Eye Contact: The eye drop, but not the dropper, must make full contact with the conjunctival sac and then be washed over the eye when the resident closes the eyelid; and - Sufficient Contact Time: The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications can be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.) o Allowing Resident to Swallow Sublingual Tablets: If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this drug. o Medication Administered Via Metered Dose Inhalers (MDI): The use of MDI in other than the following ways (this includes use of MDI by the resident). This is an error if the person administering the drug did not do all the following: - Shake the container well; - Position the inhaler in front of or in the resident's mouth. Alternatively a spacer may be used.;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		- For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used; and - If more than one puff is required, (whether the same medication or a different medication) wait approximately a minute between puffs. NOTE: If the person administering the drug follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be called a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers. Determining Medication Errors Timing Errors.. --If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a drug with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors). To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		.Prescriber's Orders. --The latest recapitulation of drug orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the drug. Procedures: §483.25(m) Medication Error Detection Methodology. --Use an observation technique to determine medication errors. The survey team should observe the administration of drugs, on several different drug "passes", when necessary. Record what is observed; and reconcile the record of observation with the prescriber's drug orders to determine whether or not medication errors have occurred. Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases. In some cases paper review can help identify actual errors but research has shown that the procedure is time consuming for the number of actual errors detected. Observation Technique. --The survey team must know without doubt, what drugs, in what strength, and dosage forms, are being administered. This is accomplished prior to drug administration and may be done in a number of ways depending on the drug distribution system used (e.g. unit dose, vial system, punch card). 1. Identify the drug product. There are two principal ways to do this. In most cases, they are used in combination:

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		. o Identify the product by its size, shape, and color. Many drug products are identifiable by their distinctive size, shape, or color. This technique is problematic because not all drugs have distinctive sizes, shapes, or color. o Identify the product by observing the label. When the punch card or the unit dose system is used, the survey team can usually observe the label and adequately identify the drug product. When the vial system is used, observing the label is sometimes more difficult. Ask the nurse to identify the medication being administered. 2. Observe and record the administration of drugs ("pass"). Follow the person administering drugs and observe residents receiving drugs (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process. Make every effort to observe residents during several different drug "passes, " if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one drug pass. Identifying residents can present a problem. The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents. 3. Reconcile the surveyor's record of observation with physician's orders. Compare the record of observation with the most current orders for drugs. This comparison involves two distinct activities: o For each drug on the surveyor's list: Was it administered according to the prescriber's orders? For example, in the correct strength, by the correct route? Was there a valid order for the drug? Was the drug the correct one? o For drugs not on the surveyor's list: Are there orders for drugs that should have been administered, but were not? Examine the record for drug orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		Ask the person administering drugs, if possible, to describe the system for administering the drugs given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed drugs, etc. Sometimes people may share medication carts. Under these circumstances, these individuals should be interviewed about the omitted dose, if they were involved, if possible. When persons that were actually responsible for administering the drugs are not available, ask their supervisor for clarification. The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error with the person who administered the drugs if possible. There may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order. 4. Reporting Errors - Describe to the facility each error that the survey team detects (e.g., Mary Jones received digoxin in 0.125 instead of 0.25 mg). The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided. 5. Observe Many Individuals Administering Medications: Strive to observe as many individuals administering medications as possible. This provides a better picture of accuracy of the facility's entire drug distribution system.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F333 (Cont)		Dose Reconciliation Technique: Supplement to the Observation Technique. --When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable the survey team to learn how frequently an error has occurred in the past. Learning about the frequency of an error can assist in judging the significance of the error. (See Significant and Non Significant Medication Errors above.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of drugs with the number of days the drug has been in use and the directions for use. For example, if a drug were in use for 5 days with direction to administer the drug 4 times a day, then 20 doses should have been used. If a count of the supply of that drug shows that only 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., resident refused the dose, or resident was hospitalized), then two omission errors may have occurred. Use the dose reconciliation technique in facilities that indicate the number of drugs received, and the date and the specific "pass" when that particular drug was started. Unless this information is available, do not use this technique. If this information is not available, there is no Federal authority under which the survey team may require it, except for controlled drugs.
F353	§483.30 Nursing services. The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.	Intent: §483.30 To assure that sufficient qualified nursing staff are available on a daily basis to meet residents' needs for nursing care in a manner and in an environment which promotes each resident's physical, mental and psychosocial well-being, thus enhancing their quality of life. Procedures: §483.30 §483.30 (a) and (b) are to be reviewed during the standard survey whenever quality of care problems have been discovered (see Appendix P, Task 4 for further information and Task 5C for the investigative protocol to complete this review). In addition, fully review requirements of nursing services during an extended survey or when a waiver of RN and/or licensed nurse (RN/LPN) staffing has been requested or granted. Except as licensed nursing personnel are

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F353	(a) Sufficient staff. (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans: (i) Except when waived under paragraph (c) of this section, licensed nurses; and (ii) other nursing personnel. (2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.	specifically required by the regulation (e.g., an RN for 8 consecutive hours a day, 7 days a week), the determination of sufficient staff will be made based on the staff's ability to provide needed care to residents that enable them to reach their highest practicable physical, mental and psychosocial well-being. The ability to meet the requirements of §§483.13, 483.15(a), 483.20, 483.25 and 483.65 determines sufficiency of nurse staffing. Guidelines: §483.30(a) and (b) At a minimum, "staff" is defined as licensed nurses (RNs and/or LPNs/LVNs), and nurse aides. Nurse aides must meet the training and competency requirements described in §483.75(e). "Full time" is defined as working 35 or more hours a week. Except for licensed staff noted above, the determining factor in sufficiency of staff (including both numbers of staff and their qualifications) will be the ability of the facility to provide needed care for residents. A deficiency concerning staffing should ordinarily provide examples of care deficits caused by insufficient quantity and quality of staff. If, however, inadequate staff (either the number or category) presents a clear threat to residents reaching their highest practicable level of well-being, cite this as a deficiency. Provide specific documentation of the threat. The facility is required to designate an RN to serve as DON on a full time basis. This requirement can be met when RNs share the position. If RNs share the DON position, the total hours per week must equal 40. Facility staff must understand the shared responsiblities. The facility can only be waived from this requirement if it has a waiver under subsection (c) or (d). Probes: §483.30(a) and (b) Determine nurse staffing sufficiency for each unit: o Is there adequate staff to meet direct care needs, assessments, planning, evaluation, supervision? o Do work loads for direct care staff appear reasonable?
F354	(b) Registered nurse. (1) Except when waived under paragraph (c) or (d) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.	

Next Page is PP-137

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F354 Cont.	(2) Except when waived under paragraph (c) or (d) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis. (3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.	o Do residents, family, and ombudsmen report insufficient staff to meet resident needs? o Are staff responsive to residents' needs for assistance, and call bells answered promptly? o Do residents call out repeatedly for assistance? o Are residents, who are unable to call for help, checked frequently (e.g., each half hour) for safety, comfort, positioning, and to offer fluids and provision of care? o Are identified care problems associated with a specific unit or tour of duty? o Is there a licensed nurse that serves as a charge nurse (e.g., supervises the provision of resident care) on each tour of duty (if facility does not have a waiver of this requirement)? o What does the charge nurse do to correct problems in nurse staff performance? o Does the facility have the services of an RN available 8 consecutive hours a day, 7 days a week (if this requirement has not been waived)? o How does the facility assure that each resident receives nursing care in accordance with his/her plan of care on weekends, nights, and holidays? o How does the sufficiency (numbers and categories) of nursing staff contribute to identified quality of care, resident rights, quality of life, or facility practices problems?
	(c) Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis. To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if -- (1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;	Intent: §483.30(c) To give the facility flexibility, in limited circumstances, when the facility cannot meet nurse staffing requirements. Guidelines: §483.30(c) The facility may request a waiver of the RN requirement, and/or the 24-hour licensed nurse requirement. If the facility is Medicaid-certified only, the State has the authority to grant the waiver. If the facility is dually-participating, HCFA has the delegated authority to grant the waiver. (See guidelines for §483.30(d).) A survey of Nursing Services must be conducted if a waiver has been granted or requested.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F355	(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility; (3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility; (4) A waiver granted under the conditions listed in paragraph (c) of this section is subject to annual State review; (5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel; (6) The State agency granting a waiver of such requirements provides notice of the waiver to the State long term care ombudsman (established under section 307 (a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and (7) The nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.	Probes: §483.30(c) Before granting a continuation of this waiver, or during the annual review, at a minimum, determine: o Is a continuing effort being made to obtain licensed nurses? o How does the facility ensure that residents' needs are being met? o Are all nursing policies and procedures followed on each shift during times when licensed services are waived? o Is there a qualified person to assess, evaluate, plan and implement resident care? o Is care being carried out according to professional practice standards on each shift? o Can the survey team ensure the State that the absence of licensed nurses will NOT endanger the health or safety of residents? o Are there trends in the facility, which might be indicators of decreased quality of care as a result of insufficient staffing to meet resident needs (e.g., increases in incident reports, the infection rate, hospitalizations)? o Are there increases in loss of function, pressure sores, tube feedings, catheters, weight loss, mental status? o Is there evidence that preventive measures (e.g., turning, ambulating) are taken to avoid poor quality of care outcomes and avoidable sudden changes in health status? o Is there evidence that sudden changes in resident health status and emergency needs are being properly identified and managed by appropriate facility staff and in a timely manner? o If the facility has a waiver of the requirement to provide licensed nurses on a 24-hour basis, have they notified the ombudsman, residents, surrogates or legal representatives, and members of their immediate families of the waiver, and are there services residents need that are not provided because licensed nurses are not available? o Is there an increase in hospitalizations because licensed personnel are not available to provide appropriate services? o Does the facility meet all applicable requirements to continue to receive a waiver? o Does the staff indicate that an RN or physician is available to respond immediately to telephone calls when licensed nurses are not available?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(d) SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week. (1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that -- (i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area; (ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and (iii) The facility either-- (A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period or; (B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days	Guidelines: §483.30(d) HCFA is delegated the waiver authority for SNFs, including dually-participating facilities (SNF/NFs). The Medicare waiver authority is far more limited than is the States' authority under Medicaid since a State may waive any element of the nurse staffing requirement, whereas the Secretary may waive only the RN requirement. The requirements that a registered nurse provide services for 8 hours a day, 7 days a week (more than 40 hours a week), and that there be an RN designated as director of nursing on a full-time basis, may be waived by the Secretary in the following circumstances: o The facility is located in a rural area with an inadequate supply of SNF services to meet area needs. Rural is defined as "all areas not delineated as `urban` by the Bureau of Census, based on the most recent census; o The facility has one full-time registered nurse regularly working 40 hours a week. This may be the same individual, or part-time individuals. This nurse may or may not be the DON, and may perform some DON and some clinical duties if the facility so desires; **and** either; o The facility has only residents whose physicians have noted, in writing, do not need RN or physician care for a 48 hour period. This does not relieve the facility from responsibility for providing for emergency availability of a physician, when necessary, nor does it relieve the facility from being responsible for meeting all needs of the residents during those 48 hours; or o A physician or RN will spend the necessary time at the facility to provide care residents need during the days that an RN is not on duty. This requirement refers to clinical care of the residents that need skilled nursing services. If a waiver of this requirement has been granted, conduct a survey of nursing services during each certification survey. Dually-participating facilities must meet the waiver provisions of the SNF. Probes: §483.30(d) If the SNF has a waiver of the more than 40 hours a week RN requirement: o Is there an RN on duty 40 hours a week? o If more than one RN provides the 40 hour per week coverage, how is information exchanged that maintains continuity of resident care? o Does each clinical record have documentation by the physician that the resident does not need services of a physician or an RN for a 48 hour period each week. o Are there any emergency or routine services that should be, but are not, provided to residents during the days that a registered nurse is not on duty? o If specific skilled care is necessary for a resident during the time that an RN is not on duty, does an RN or physician provide that service on an "as needed" basis? o Did the facility notify residents (or their legal guardians) and their immediate families about the waiver and the ombudsman?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	when the regular full-time registered nurse is not on duty; (iv) The Secretary provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and (v) The facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver. (2) A waiver of the registered nurse requirement under paragraph (d)(1) of this section is subject to annual renewal by the Secretary.	See also probes at §483.30(c). If the SNF requests continuation of the waiver to provide the services of a registered nurse for more than 40 hours a week, the survey team is to provide the Secretary with information needed to grant this continuation. o Does the SNF meet all requirements necessary for continuation of the waiver? Procedures: §483.30(a)-(d) If the facility has an approved nurse staffing waiver, it is not considered a deficiency. The facility does not need to submit a POC. The following procedure should be used to document that a facility has a waiver of nurse staffing requirements. When a facility does not meet the nurse staffing requirements, cite the appropriate tag. If the facility does have a waiver, reference the tag number based on the type of facility. The type of facility (SNF, NF, or SNF/NF) determines what type of waiver is granted: o For SNFs and SNF/NFs which may be waived from the requirement to provide more than 40 hours of registered nurse services a week, and for NFs which have been granted a waiver from the 56 hour registered nurse requirement, cite F354; o For NFs that have a waiver of the 24-hour licensed nursing requirement, cite F353; or o Both facility types could be waived for the requirement to designate a registered nurse as the director of nursing on a full-time basis. Cite F355. When the HCFA-2567 is entered into OSCAR, code the waived tag as a "W". Enter the tag number, leave the correction date blank, and enter a "W" in the CP field. This will indicate that this is not a deficiency--that the requirement has been waived.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F360	§483.35 Dietary Services. The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.	Intent: §483.35(a) The intent of this regulation is to ensure that a qualified dietitian is utilized in planning, managing and implementing dietary service activities in order to assure that the residents receive adequate nutrition. A director of food services has no required minimum qualifications, but must be able to function collaboratively with a qualified dietitian in meeting the nutritional needs of the residents.
F361	(a) Staffing. The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis. (1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian. (2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.	Guidelines: §483.35(a) A dietitian qualified on the basis of education, training, or experience in identification of dietary needs, planning and implementation of dietary programs has experience or training which includes: o Assessing special nutritional needs of geriatric and physically impaired persons; o Developing therapeutic diets; o Developing "regular diets" to meet the specialized needs of geriatric and physically impaired persons; o Developing and implementing continuing education programs for dietary services and nursing personnel; o Participating in interdisciplinary care planning; o Budgeting and purchasing food and supplies; and o Supervising institutional food preparation, service and storage. Procedures: §483.35(a) If resident reviews determine that residents have nutritional problems, determine if these nutritional problems relate to inadequate or inappropriate diet nutrition/assessment and monitoring. Determine if these are related to dietitian qualifications. Probes: §483.35(a) If the survey team finds problems in resident nutritional status: o Do practices of the dietitian or food services director contribute to the identified problems in residents' nutritional status? If yes, what are they?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F361 Cont.		o What are the educational, training, and experience qualifications of the facility's dietitian?
F362	(b) Sufficient staff. The facility must employ sufficient support personnel competent to carry out the functions of the dietary service.	Guidelines: §483.35(b) "Sufficient support personnel" is defined as enough staff to prepare and serve palatable, attractive, nutritionally adequate meals at proper temperatures and appropriate times and support proper sanitary techniques being utilized. Procedures: §483.35(b) For residents who have been triggered for a dining review, do they report that meals are palatable, attractive, served at the proper temperatures and at appropriate times? Probes: §483.35(b) (Sufficient staff preparation) Is food prepared in scheduled timeframes in accordance with established professional practices? Observe food service: Does food leave kitchen in scheduled timeframes? Is food served to residents in scheduled timeframes?
F563	(c) Menus and nutritional adequacy. Menus must-- (1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;	Intent: §483.35(c)(1)(2)(3) The intent of this regulation is to assure that the meals served meet the nutritional needs of the resident in accordance with the recommended dietary allowances (RDA's) of the Food and Nutrition Board of the National Research Council, of the National Academy of Sciences. This regulation also assures that there is a prepared menu by which nutritionally adequate meals have been planned for the resident and followed. Procedures: §483.35(c)(1) o For sampled residents who have a comprehensive review or a focused review, as appropriate, observe if meals served are consistent with the planned menu and care plan in the amounts, types and consistency of foods served.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F363 Cont.		If the survey team observes deviation from the planned menu, review appropriate documentation from diet card, record review, and interviews with food service manager or dietitian to support reason(s) for deviation from the written menu. Probes: §483.35(c)(1) o Are residents receiving food in the amount, type, consistency and frequency to maintain normal body weight and acceptable nutritional values? o If food intake appears inadequate based on meal observations, or resident's nutritional status is poor based on resident review, determine if menus have been adjusted to meet the caloric and nutrient-intake needs of each resident. o If a food group is missing from the resident's daily diet, does the facility have an alternative means of satisfying the resident's nutrient needs? If so, does the facility perform a follow-up? (Menu adequately provides the daily basic food groups) Does the menu meet basic nutritional needs by providing daily food in the groups of the food pyramid system and based on individual nutritional assessment taking into account current nutritional recommendations? NOTE: A standard meal planning guide (e.g., food pyramid) is used primarily for menu planning and food purchasing. It is not intended to meet the nutritional needs of all residents. This guide must be adjusted to consider individual differences. Some residents will need more due to age, size, gender, physical activity, and state of health. There are many meal planning guides from reputable sources, i.e., American Diabetes Association, American Dietetic Association, American Medical Association, or U.S. Department of Agriculture, that are available and appropriate for use when adjusted to meet each resident's needs.
	(2) Be prepared in advance; and	Probes: §483.35(c)(2) (Menu prepared in advance) Are there preplanned menus for both regular and therapeutic diets?
	(3) Be followed.	Probes: §483.35(c)(3) (Menu followed) Is food served as planned? If not, why? There may be legitimate and extenuating circumstances why food may not be available on the day of the survey and must be considered before a concern is noted.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(d) Food. Each resident receives and the facility provides--	Intent: §483.35(d)(1)(2) The intent of this regulation is to assure that the nutritive value of food is not compromised and destroyed because of prolonged food storage, light, and air exposure; prolonged cooking of foods in a large volume of water and prolong holding on steam table, and the addition of baking soda. Food should be palatable, attractive, and at the proper temperature as determined by the type of food to ensure resident's satisfaction. Refer to §483.15(e) and/or §483.15(a). Guidelines: §483.35(d)(1) "Food-palatability" refers to the taste and/or flavor of the food. "Food attractiveness" refers to the appearance of the food when served to residents. Procedures: §483.35(d)(1) Evidence for palatability and attractiveness of food, from day to day and meal to meal, may be strengthened through sources such as: additional observation, resident and staff interviews, and review of resident council minutes. Review nutritional adequacy in §483.25(i)(l). Probes: §483.35(d)(1)(2) Does food have a distinctly appetizing aroma and appearance, which is varied in color and texture? Is food generally well seasoned (use of spices, herbs, etc.) and acceptable to residents? (Conserves nutritive value) Is food prepared in a way to preserve vitamins? Method of storage and preparation should cause minimum loss of nutrients. (Food - temperature) Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the resident and customary practice? Not to be confused with the proper holding temperature.
F364	(1) Food prepared by methods that conserve nutritive value, flavor, and appearance; (2) Food that is palatable, attractive, and at the proper temperature;	
F365	(3) Food prepared in a form designed to meet individual needs; and	Intent: §483.35(d)(3)(4) The intent of this regulation is to assure that food is served in a form that meets the resident's needs and satisfaction; and that the resident receives appropriate nutrition when a substitute is offered.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F366	(4) Substitutes offered of similar nutritive value to residents who refuse food served.	Procedures: §483.35(d)(3)(4) Observe trays to assure that food is appropriate to resident according to assessment and care plan. Ask the resident how well the food meets their taste needs. Ask if the resident is offered or is given the opportunity to receive substitutes when refusing food on the original menu. Probes: §483.35(d)(3)(4) Is food cut, chopped, or ground for individual resident's needs? Are residents who refuse food offered substitutes of similar nutritive value? Guidelines: §483.35(d)(4) A food substitute should be consistent with the usual and ordinary food items provided by the facility. For example, if a facility never serves smoked salmon, they would not be required to serve this as a food substitute; or the facility may, instead of grapefruit juice, substitute another citrus juice or vitamin C rich juice that the resident likes. Intent: §483.35(e) The intent of this regulation is to assure that the resident receives and consumes foods in the appropriate form and/or the appropriate nutritive content as prescribed by a physician and/or assessed by the interdisciplinary team to support the treatment and plan of care. Guidelines: §483.35(e) "Therapeutic Diet" is defined as a diet ordered by a physician as part of treatment for a disease or clinical condition, or to eliminate or decrease specific nutrients in the diet, (e.g., sodium) or to increase specific nutrients in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet). "Mechanically altered diet" is one in which the texture of a diet is altered. When the texture is modified, the type of texture modification must be specific and part of the physicians' order. Procedures: §483.35(e) If the resident has inadequate nutrition or nutritional deficits that manifests into and/or are a product of weight loss or other medical problems, determine if there is a therapeutic diet that is medically prescribed. Probes: §483.35(e) Is the therapeutic diet that the resident receives prescribed by the physician?
F367	(e) Therapeutic diets. Therapeutic diets must be prescribed by the attending physician.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F367 Cont.		Also, see §483.25(i), Nutritional Status.
F368	(f) Frequency of meals. (1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community. (2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below. (3) The facility must offer snacks at bedtime daily. (4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.	Intent: §483.35(f)(1)(2)(3)(4) The intent of this regulation is to assure that the resident receives his/her meals at times most accepted by the community and that there are not extensive time lapses between meals. This assures that the resident receives adequate and frequent meals. Guidelines: §483.35(f)(1)(2)(3)(4) A "substantial evening meal" is defined as an offering of three or more menu items at one time, one of which includes a high-quality protein such as meat, fish, eggs, or cheese. The meal should represent no less than 20 percent of the day's total nutritional requirements. "Nourishing snack" is defined as a verbal offering of items, single or in combination, from the basic food groups. Adequacy of the "nourishing snack" will be determined both by resident interviews and by evaluation of the overall nutritional status of residents in the facility, (e.g., Is the offered snack usually satisfying?) Procedures: §483.35(f)(1)(2)(3)(4) Observe meal times and schedules and determine if there is a lapse in time between meals. Ask for resident input on meal service schedules, to verify if there are extensive lapses in time between meals.
F369	(g) Assistive devices. The facility must provide special eating equipment and utensils for residents who need them.	Intent: §483.35(g) The intent of this regulation is to provide residents with assistive devices to maintain or improve their ability to eat independently. For example, improving poor grasp by enlarging silverware handles with foam padding, aiding residents with impaired coordination or tremor by installing plate guards, or providing postural supports for head, trunk, and arms.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F369 Cont.		Procedures: §483.35(g) Review sampled residents comprehensive assessment for eating ability. Determine if recommendations were made for adaptive utensils and if they were, determine if these utensils are available and utilized by resident. If recommended but not used, determine if this is by resident's choice. If utensils are not being utilized, determine when these were recommended and how their use is being monitored by the facility and if the staff is developing alternative recommendations.
	(h) Sanitary conditions. The facility must--	Intent: §483.35(h)(2) The intent of this regulation is to prevent the spread of food borne illness and reduce those practices which result in food contamination and compromised food safety in nursing homes. Since foodborne illness is often fatal to nursing home residents, it can and must be avoided.
F370	(1) Procure food from sources approved or considered satisfactory by Federal, State or local authorities;	
F371	(2) Store, prepare, distribute, and serve food under sanitary conditions; and	Guidelines: §483.35(h)(2) "Sanitary conditions" is defined as storing, preparing, distributing, and serving food properly to prevent food borne illness. Potentially hazardous foods must be subject to continuous time/temperature controls in order to prevent either the rapid and progressive growth of infectious or toxigenic micro-organisms such as Salmonella or the slower growth of Clostridium Botulinum. In addition, foods of plant origin become potentially hazardous when the skin, husk, peel, or rind is breached, thereby possibly contaminating the fruit or vegetable with disease causing micro-organisms. Potentially hazardous food tends to focus on animal products, including but not limited to milk, eggs and poultry. Improper holding temperature is a common contributing factor of foodborne illness. The facility must follow proper procedures in cooking, cooling, and storing food according to time, temperatures, and sanitary guidelines. Improper handling of food can cause salmonella and E-coli contamination. The 1993 FDA Food Code advises the following precautions: NOTE: The 1993 FDA Food Code is not regulation and cannot be enforced as such. The food temperatures cited that are recommended in the 1993 FDA Food Code are target temperatures and give a margin of safety in temperature ranges and to avoid known harmful temperatures.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F371 Cont.		Refrigerator storage of food to prevent food borne illness includes storing raw meat away from vegetables and other foods. Raw meat should be separated from cooked foods and other foods when refrigerated on its own tray on a bottom shelf so meat juices do not drip on other foods. Foods of both plant and animal origin must be cooked, maintained and stored at appropriate temperatures. o Foods of both plant and animal origin must be cooked, and maintained, and stored at appropriate temperatures. These temperatures are better utilized as food hold temperatures rather than the food temperatures as residents receive the food. o Hot foods which are potentially hazardous should leave the kitchen (or steam table) above 140° F, and cold foods at or below 41° F and freezer temperatures should be at 0° F or below. Refrigerator temperatures should be maintained at 41° F or below. The 1993 FDA Food Code can be used as an authoritative guide to clarify regulatory requirements on how to prepare and serve food to prevent foodborne illness. As the public becomes more informed and educated on how to prevent foodborne illness, this code will become the standard of practice the same as the 1976 Food Service Sanitation Manual did prior to 1993. Procedures: §483.35(h)(2) Observe storage, cooling, and cooking of food. Record the time and date of all observations. If a problem is noted, conduct additional observations to verify findings. Observe that employees are effectively cleaning their hands prior to preparing, serving and distributing food. Observe that food is covered to maintain temperature and protect from other contaminants when transporting meals to residents. Refrigerated storage: Check all refrigerators and freezers for temperatures. Use the facility's or the surveyor's own properly sanitized thermometer to evaluate the internal temperatures of potentially hazardous foods with a focus on the quantity of leftovers and the container sizes in which bulk leftovers are stored. Food preparation: Use a sanitized thermometer to evaluate food temperatures. In addition, how do kitchen staff process leftovers? Are they heated to the appropriate temperatures? How is frozen food thawed? How is potentially hazardous food handled during multi-step food preparation (e.g., chicken salad, egg salad)? Is hand contact with food minimized? Food service: Using a properly sanitized thermometer, check the temperatures of hot and cold food prior to serving. How long is milk held without refrigeration prior to distribution? Food distribution: Is the food protected from contamination as it is transported to the dining rooms and residents' rooms?

TAG		

NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F371 Cont.		Pest free: Is the area pest free? (See §483.70(h)(4).) Look for signs of pests such as mice, roaches, rates, flies. (Preventing Contamination) Are handwashing facilities convenient and properly equipped for dietary services staff Use? (Staff uses good hygienic practices and staff with communicable disease or infected skin lesions do not have contact with food if that contact will transmit the disease.) (Hazard Free) Are toxic items (such as insecticides, detergent, polishes) properly stored, labeled, and used separate from the food? Probes: §483.35(h)(2) Observe food storage rooms and food storage in the kitchen. Are containers of food stored off the floor and on clean surfaces in a manner that protects it from contamination? Are other areas under storage shelves monitored for cleanliness to reduce attraction of pest. Are potentially hazardous foods stored at 41° F or below and frozen foods kept at 0° F or below? Do staff handle and cook potentially hazardous foods properly? Are potentially hazardous foods kept at an internal temperature of 41° F or below in cold food storage unit, or at an internal temperature of 140° F or above in a hot food storage unit during display and service? Is food transported in a way that protects against contamination (i.e., covered containers, wrapped, or packaged)? Is there any sign of rodent or insect infestation. (Dishwashing) The current 1993 Food Code, DHHS, FDA, PHS recommends the following water temperature and manual washing instructions: MACHINE: 1. Hot Water: a. 140° F Wash (or according to the manufacturer's specifications or instructions). b. 180° F Rinse (180°, 160° or greater at the rack and dish/utensils surfaces. 2. Low Temperature: a. 120° F +25 ppm (parts per million) Hypochlorite (household bleach) on dish Surface.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F371 Cont.		MANUAL: 1. 3 Compartment Sink (wash, rinse and sanitize): Sanitizing solution used according to manufacturer's instructions. a. 75° F - 50 ppm Hypochlorite (household bleach) or equivalent, or 12.5 ppm of Iodine. b. Hot Water Immersion at 170° F for at least 30 seconds. (Dishwashing) Are food preparation equipment, dishes, and utensils effectively sanitized and cleaned to destroy potential disease carrying organisms and stored in a protected manner?
F372	(3) Dispose of garbage and refuse properly.	Guidelines: §483.35(h)(3) The intent of this regulation is to assure that garbage and refuse be properly disposed. Procedures: §483.35(h)(3) (Garbage/refuse) Observe garbage and refuse container construction, and outside storage receptacles. Probes: §483.35(h)(3) Are garbage and refuse containers in good condition (no leaks) and is waste properly contained in dumpsters or compactors with lids or otherwise covered? Are areas such as loading docks, hallways, and elevators used for both garbage disposal and clean food transport kept clean, free of debris and free of foul odors and waste fat? Is the garbage storage area maintained in a saunter condition to prevent the harborage and feeding of pests? Are garbage receptacles covered when being removed from the kitchen area to the dumpster?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F385	§483.40 Physician Services. A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. (a) Physician supervision. The facility must ensure that-- (1) The medical care of each resident is supervised by a physician; and (2) Another physician supervises the medical care of residents when their attending physician is unavailable.	Intent: §483.40 The intent of this regulation is to ensure the medical supervision of the care of nursing home residents by a personal physician. Guidelines: §483.40 A physician's "personal approval" of an admission recommendation must be in written form. The physician's admission orders for the resident's immediate care as required in §483.20(a) will be accepted as "personal approval" of the admission. "Supervising the medical care of residents" means participating in the resident's assessment and care planning, monitoring changes in resident's medical status, and providing consultation or treatment when called by the facility. It also includes, but is not limited to, prescribing new therapy, ordering a resident's transfer to the hospital, conducting required routine visits or delegating and supervising follow-up visits to nurse practitioners or physician assistants. Each resident should be allowed to designate a personal physician. (See §483.10(d)(1).) The facility's responsibility in this situation is to simply assist the resident, when necessary, in his or her efforts to obtain those services. For example, the facility could put the resident in touch with the county medical society for the purpose of obtaining referrals to practicing physicians in the area. Facilities should share MDS and other assessment data with the physician. Procedures: §483.40 If there is a deficiency in §483.10, Resident rights; §483.13, Resident behavior and facility practices; §483.15, Quality of life; or §483.25, Quality of care, fully review all of the tags under this requirement. Probes: §483.40(a) o How was the supervising physician involved in the resident's assessment and care planning? o If staff reported a significant change in medical status to the supervising physician, did the physician respond? o If the supervising physician was unavailable and could not respond, did the facility have a physician on call? Did this physician respond? o Are residents sent to hospital emergency rooms routinely because the facility does not always have a physician on call?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(b) Physician visits. The physician must--	Intent: § 483.40(b) The intent of this regulation is to have the physician take an active role in supervising the care of residents. This should not be a superficial visit, but should include an evaluation of the resident's condition and a review of and decision about the continued appropriateness of the resident's current medical regime.
F386	(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section; (2) Write, sign, and date progress notes at each visit; and (3) Sign and date all orders.	Guidelines: §483.40(b) Total program of care includes all care the facility provides residents to maintain or improve their highest practicable mental and physical functional status, as defined by the comprehensive assessment and plan of care. Care includes medical services and medication management, physical, occupational, and speech/language therapy, nursing care, nutritional interventions, social work and activity services that maintain or improve psychosocial functioning. The physician records residents' progress and problems in maintaining or improving their mental and physical functional status. The physician need not review the total plan of care at each visit, but must review the total plan of care at visits required by §483.40(c). There is no requirement for physician renewal of orders. In cases where facilities have created the option for a resident's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. See Guidelines for §483.75(1)(1) for information on facility safeguards concerning electronic signatures. Physician orders may be transmitted by facsimile machine if the following conditions are met: o The physician should have signed and retained the original copy of the order from which the facsimile was transmitted and be able to provide it upon request. Alternatively, the original may be sent to the facility at a later time and substituted for the facsimile. o The facility should photocopy the faxed order since some facsimiles fade over time. The facsimile copy can be discarded after facility photocopies it. o A facility using such a system should establish adequate safeguards to assure that it is not subject to abuse. It is not necessary for a physician to re-sign the facsimile order when he/she visits the facility. When rubber stamp signatures are authorized by the facility's management, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes and written signatures must be readily available and maintained under adequate safeguards.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F386 Cont.		Probes: §483.4(b) o Do services ordered by a physician show a pattern of care to maintain or improve the resident's level of independent functioning? For example, how do physician orders reflect the resident's nutritional status and needs? o Does documentation reflect continuity of care in maintaining or improving a resident's mental and physical functional status? For example, do the attending physician's rehabilitation service orders show a pattern of consistent restorative programming?
	(c) Frequency of physician visits.	Guidelines: §483.40(c) "Must be seen" means that the physician must make actual face-to-face contact with the resident. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.
F387	(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter. (2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.	After the initial physician visit in SNFs, where States allow their use, a qualified nurse practitioner (NP), clinical nurse specialist or physician assistant (PA) may make every other required visit. (See §483.40(e) Physician delegation of tasks in SNFs.) In a NF, the physician visit requirement, in accordance with the State law, may be satisfied by NP, clinical nurse specialist or PA. (See §483.40 (f).)
F388	(3) Expect as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally. (4) At the option of the physician, required visits in SNF's, after the initial visit, may alternate between personal visits by the physician and visits by a	The timing of physician visits is based on the admission date of the resident. Visits will be made within the first 30 days, and then at 30 day intervals up until 90 days after the admission date. Visits will then be at 60 day intervals. Permitting up to 10 days slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident at least every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.40(c). Policy that allows an NP, clinical nurse specialist, or PA to make every other required visit, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident's medical condition makes that visit necessary. It is expected that visits will occur at the facility rather than the doctor's office unless office equipment is needed or a resident specifically requests an office visit. If the facility has established policy that residents leave the grounds for medical care, the resident does not object, and this policy does not infringe on his/her

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F388 Cont.	physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.	rights, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with §483.10(b). Probes: §483.40(c) o How does the scheduling and frequency of physician visits relate to any identified quality of care problems? o When a PA, clinical nurse specialist, or NP performs a delegate physician visit, and determines that the resident's condition warrants direct contact between the physician and the resident, does the physician follow-up promptly with a personal visit?
F389	(d) Availability of physicians for emergency care. The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.	Guidelines: §483.40(d) If a resident's own physician is unavailable, the facility should attempt to contact that physician's designated referral physician before assuming the responsibility of assigning a physician. Arranging for physician services may include assuring resident transportation to a hospital emergency room/ward or other medical facility if the facility is unable to provide emergency medical care at the facility. Probes: §483.40(d) o Does the facility have a physician on call for medical emergencies? Does this physician respond? o For what reasons are residents sent to hospital emergency rooms? o Did medical management of the emergency affect the resident's maintaining or improving their functional abilities? o If the resident refused the physician's visit, what has the facility done to explain to the resident the results and alternatives that may be available?
F390	(e) Physician delegation of tasks in SNFs. (1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who--	Guidelines: §483.40(e) "Nurse practitioner" is a registered professional nurse now licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners. "Clinical nurse specialist" is a registered professional nurse currently in practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F390 Cont.	(i) Meets the applicable definition in §491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State; (ii) Is acting within the scope of practice as defined by State law; and (iii) Is under the supervision of the physician. (2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.	"Physician assistant" is a person who meets the applicable State requirements governing the qualifications for assistants to physician. When personal performance of a particular task by a physician is specified in the regulations, performance of that task cannot be delegated to anyone else. The tasks of examining the resident, reviewing the resident's total program of care, writing progress notes, and signing orders may be delegated according to State law. The extent to which physician services are delegated to physician extenders in SNFs will continue to be determined by the provisions of §483.40(e), while the extent to which these services are performed by physician extenders in NFs will be determined by the individual States under §483.40(f). Probes: §483.40(e) o Do the facility's attending physicians delegate to NPs, clinical nurse specialists, or PAs? o Do NP/clinical nurse specialist/PA progress notes and orders follow the scope of practice allowed by State law? o What evidence is there of physician supervision of NPs or PAs? For example, do physicians countersign NP/PA orders, if required by State law?
	(f) Performance of physician tasks in NFs. At the option of State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.	Guidelines: §483.40(f) If delegation of physician tasks is permitted in your State and the physician extender does not meet the qualifications listed here, cite F388. Procedures: §483.40(f) If a nurse practitioner, clinical nurse specialist, or physician assistant is performing required physician tasks in a NF, is this allowed by the State? Is this person an employee of the facility? (Facility employees are prohibited from serving in this capacity.) Probes: §483.40(f) Is this person working in collaboration with the physician?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§483.45 Specialized rehabilitative services.	Intent: §483.45(a)(1)(2) The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psycho-social well-being. "Specialized rehabilitative services" are differentiated from restorative services which are provided by nursing staff. Specialized rehabilitative services are provided by or coordinated by qualified personnel. Specialized rehabilitative services are considered a facility service and are, thus, included within the scope of facility services. They must be provided by or coordinated by qualified personnel. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services. A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the services from an outside resource. For a resident with MI or MR to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self-determination as possible. They are: "Specialized services for MI or MR" refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the NF (e.g., outside the NF setting), because the overall level of NF services is not as intense as necessary to meet the individual's needs. The Preadmission Screening and Annual Resident Review (PASARR) report indicates specialized services required by the resident. The State is required to list those services in the report, as well as provide or arrange for the provision of the services. If the State determines that the resident does not require specialized services, the facility is responsible to provide all services necessary to meet the resident's mental health or mental retardation needs. "Mental health rehabilitative services for MI and MR", refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they are required to be subject to the PASARR process and whether or not they require additional services to be provided or arranged for by the State as specialized services.
F406	(a) Provision of services. If specialized rehabilitative services such as, but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must-- (1) Provide the required services; or (2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F406 Cont.		The facility should provide interventions which complement, reinforce and are consistent with any specialized services (as defined by the resident's PASARR) the individual is receiving or is required to receive by the State. The individual's plan of care should specify how the facility will integrate relevant activities throughout all hours of the individual's day at the NF to achieve this consistency and enhancement of PASARR goals. The surveyor should see competent interaction by staff at all times, in both formal and informal settings in accordance with the individual's needs. Mental health rehabilitative services for MI and MR may include, but are not limited to: o Consistent implementation during the resident's daily routine and across settings, of systematic plans which are designed to change inappropriate behaviors; o Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness; o Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal); o Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self-determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment; o Crisis intervention service; o Individual, group, and family psychotherapy; o Development of appropriate personal support networks; and o Formal behavior modification programs. Procedures: §483.45(a)(1)(2) For sampled residents, whose comprehensive assessment indicates physical, psychosocial, and/or communications rehabilitation potential (See MDS Sections E, C, G, H. In version 2.0, sections G, C, F, E. References to version 2.0 of the MDS are effective when the State respecifies its RAI), observe for unmet needs for rehabilitative services. Determine the extent of follow through with comprehensive care plan using probes outlined below. Verify from the chart that resident is receiving frequency and type of therapy as outlined in the care plan. Probes: §483.45(a)(1)(2) 1. (For physical therapy) a. What did the facility do to improve the resident's muscle strength? The resident's balance? b. What did the facility do to determine if as assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function? c. If the resident has an assistive device, is he/she encouraged to use it on a regular basis?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F406 Cont.		d. What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)? e. What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence? 2. (For occupational therapy) a. What did the facility do to decrease the amount of assistance needed to perform a task? b. What did the facility do to decrease behavioral symptoms? c. What did the facility do to improve gross and fine motor coordination? d. What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration? e. What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards? 3. For speech-language pathology. a. What did the facility do to improve auditory comprehension such as understanding common, functional words, concepts of time and place, and conversation? b. What did the facility do to improve speech production? c. What did the facility do to improve the expressive behavior such as the ability to name common, functional items? d. What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received and audiologic evaluation? For example, did the facility instruct the resident how to effectively and independently use environmental controls to compensate for hearing loss such as eye contact, preferential seating, use of the better ear? e. For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication? 4. (For health rehabilitative services for MI and MR) a. What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior? b. What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal? c. What did the facility do to develop and maintain necessary daily living skills? d. How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR? e. (Questions to ask individuals with MI or MR:) (1) Who do you talk to when you have a problem or need something? (2) What do you do when you feel happy? Feel sad? Can't sleep at night? (3) In what activities are you involved, and how often?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F406 Cont.		Intent: §485.45(b) The intent of this regulation is to assure that the rehabilitative services are medically necessary as prescribed by a physician and provided by qualified personnel to maximize potential outcomes. Specialized rehabilitative services are provided for individual's under a physician's order by a qualified professional. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative sides will follow to maintain functional and physical status. Guidelines: §483.45(b)
F407	(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.	"Qualified personnel" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only by licensed or credentialed personnel. Procedures: §483.45(b) Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff. Determine from the care plan and record that rehabilitative services are provided under the written order of a physician and by qualified personnel. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it may be necessary to validate the care providers qualification. Probes: §483.45(b) If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§483.55 Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care.	Intent: §483.55 The intent of this regulation is to ensure that the facility be responsible for assisting the resident in obtaining needed dental services, including routine dental services. Guidelines: §483.55 This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents, i.e., employ a staff dentist or have a contract (arrangement) with a dentist to provide services. For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find and alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well-being. (See 1483.15(g).) The facility is responsible for selecting a dentist who provides dental services in accordance with professional standards of quality and timeliness under §483.75(h)(2). "Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures, e.g., taking impressions for dentures and fitting dentures. "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity by a dentist that required immediate attention. "Prompt referral" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures. Probes: §483.55 Do residents selected for comprehensive or focused reviews, as appropriate, with dentures use them? Are residents missing teeth and may be in need of dentures? Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? Are resident's dentures intact? Proper fit?
F411	(a) Skilled nursing facilities. A facility	
	(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident; (2) May charge a Medicare resident an additional amount for routine and emergency dental services; (3) Must if necessary assist the resident-- (i) In making appointments; and (ii) By arranging for transportation to and from the dentist's office; and (4) Promptly refer residents with lost or damaged dentures to a dentist.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F412	(b) Nursing facilities. The facility	
	(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident: (i) Routine dental services (to the extent covered under the State plan); and (ii) Emergency dental services; (2) Must, if necessary, assist the resident-- (i) In making appointments; and (ii) By arranging for transportation to and from the dentist's office; and (3) Must promptly refer residents with lost or damaged dentures to a dentist.	Guidelines: §483.55(b)(1)(i) For Medicaid residents, the facility must provide the resident, without charge, all emergency dental services, as well as those routine dental services that are covered under the State plan.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F425	§483.60 Pharmacy services. The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.	Guidelines: §483.60 The facility is responsible under §483.75(h) for the "timeliness of the services." A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met. Procedures: §483.60 During the surveyor's observation of the drug pass, are all ordered medications available?
F426	(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.	
F427	(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who-- (1) Provides consultation on all aspects of the provision of pharmacy services in the facility; (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and	Guidelines: §483.60(b)(2) and (3) A record of receipt and disposition of controlled drugs does not need to be proof of use sheets. The facility can use existing documentation such as the Medication Administration Record (MAR) to accomplish this record.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F427 (Cont.)	(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.	Periodic reconciliations should be monthly. If they reveal shortages, the pharmacist and the director of nursing may need to initiate more frequent reconciliations. In situations in which loss of controlled drugs is evident, the facility may have to utilize proof of use sheets on all controlled drugs for all shifts. However, when the source of shortage is located and remedied, the facility may go back to periodic reconciliation by the pharmacist. Please note that the regulation does not prohibit shortages of controlled drugs - only that a record be kept and that it be periodically reconciled. If the survey reveals that all controlled drugs are not accounted for, refer the case to the State nursing home licensure authority, or to the State Board of Pharmacy.
F428	(c) Drug regimen review. (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.	Guidelines: §483.60(c)(1) It may be necessary to review more frequently (e.g., every week) depending on the residents' condition and the drugs they are taking.
F429	(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and	Guidelines: 483.60(c)(2) Refer to Part One of Appendix N and the guidance described below for detailed information concerning the survey of this requirement. If the survey team finds one or more of the drug therapy circumstances in Part One of Appendix N, or in the guidance described below, and there is no documentation that the pharmacist has identified and notified the attending physician and the director of nursing, then cite this requirement. The facility is encouraged to share the pharmacist's drug regimen review report with the medical director. The medical director is responsible for coordination of medical care in the facility (see 483.75(I)(2)(ii).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		MISCELLANEOUS DRUGS THAT ARE POTENTIALLY INAPPROPRIATE IN THE ELDERLY: The following list of drugs and diagnoses/drug combinations have been partially adapted from a paper entitled "Explicit Criteria for Determining Inappropriate Medication Use by the Elderly" by Mark H. Beers, MD. This paper was published in the *Archives of Internal Medicine,* Vol. 157 July 28, 1997. The paper lists numerous drugs and diagnosis/drug combinations that are judged to place a person over the age of 65 at greater risk of adverse drug outcomes (ADR). The judgments in this paper were arrived at through an extensive review of the literature by a panel of experts. There are two important quotations from the paper that the surveyor should keep in mind at all times: 1. "These criteria were developed to predict when the potential for adverse outcomes is greater than the potential for benefit." 2. "Without measuring outcomes, criteria cannot determine whether adverse outcomes have occurred; they can only determine that they are more likely to occur." These criteria are divided into two broad categories. Drug therapy that is classified as having "high severity" and therapy that is considered as not having "high severity." Severity is defined as: "a combination of both the likelihood that an adverse outcome would occur and the clinical significance of that outcome should it occur." The survey guidelines are located in two parts, F329 and F429. The surveyor has the option to cite at either or both tags depending on the situation. 1. Drug Therapy With High Potential for Severe Adverse Outcomes in Persons Over 65 that are to be used to determine compliance with 483.25(l)(1), Unnecessary Drug (F329), and 2. Drug Therapy With High Potential for Less Severe Adverse Outcomes In Persons Over 65 that are to be used to determine compliance with 483.60(c)(1), Drug Regimen Review Report (F429) which are located under guidance to surveyors for drug regimen review. It should be noted that medication alterations may not be appropriate for some short-term residents. Many residents arrive in the long term care setting already on medications that they have managed to tolerate for years or that have been prescribed in the hospital. For some short-stay residents, it is difficult to change these medications without a period of observation and information gathering. Therefore, review by the surveyor is not necessary for drug therapy given the first seven consecutive days upon admission/readmission, unless there is an immediate threat to health and safety.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		LIST OF DRUG COMBINATIONS WITH HIGH POTENTIAL FOR LESS SEVERE ADVERSE OUTCOMES 1. Phenylbutazone (Butazolidin) **Risk: "May produce serious hematological side effects (blood disorders) and should not be used in elderly patients."** Blood disorders include bone marrow depression, aplastic anemia, agranulocytosis, leukopenia, pancytopenia, thrombocytopenia, macrocytic or megoblastic anemia. 2. Trimethobenzamide (Tigan) Risk: **"Trimethobenzamide is one of the least effective antiemetics, yet it can cause extrapyramidal side effects."** Extrapyramidal side effects may involve various combinations of tremors, postural unsteadiness, lack of or slowness of movement, cogwheel rigidity, expressionless face, drooling, infrequent blinking, shuffling gate, decreased arm swing, and rigidity of muscles in the limbs, neck, and trunk. 3. Indomethacin (Indocin, Indocin SR) Risk: **"Of all the nonsteroidal anti-inflammatory drugs, indomethacin produces the most central nervous system side effects and should therefore be avoided in the elderly."** The most common side effects (in order of frequency of occurrence) are headache (10%), dizziness (3-9%), and vertigo, somnolence, depression, and fatigue (1-3%). Exception: It is considered acceptable to use indomethacin for short term (e.g., 1 week) treatment of an acute episode of gouty arthritis. 4. Dipyridamole (Persantine) Risk: **"Dipyridamole frequently cause orthostatic hypotension in the elderly. It has been proven beneficial only in patients with artificial heart valves. Whenever possible, its use in the elderly should be avoided.**

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		5. Reserpine (Serpasil) Combination products such as Ser-Ap-Es, Serathide, Hydropses, Unipres, Uni-serp, Diutensen-R, Metatensin #2 & #4, Diupres, Hydroserpine, Hydromox-R, Regroton, Renese-R, Salutensin. Risk: **Reserpine imposes unnecessary risks in the elderly, inducing depression, impotence, sedation, and orthostatic hypotension. Safer alternatives exist."** 6. Diphenhydramine (Benadryl) Note: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329)) already has guidelines for these drugs under: D. Drugs for Sleep Induction. The surveyor should use that guideline if diphenhydramine is being used as a hypnotic. If diphenhydramine is being used as an antihistamine, this guideline should be used. Risk: **"Diphenhydramine is potently anticholinergic and usually should not be used as a hypnotic in the elderly. When used to treat or prevent allergic reactions, it should be used in the smallest dose and with great caution."** Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. Exception: For treatment of allergies, review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. 7. Ergot Mesyloids (Hydergine), Cyclandelate (Cyclospasmol) Risk: **"Hydergine and the central vasodilators have not been shown to be effective, in the doses studied for treatment of dementia or any other condition."** 8. Muscle Relaxants Muscle Relaxants such as Methocarbamol (Robaxin), Carisoprodol (Soma), Chlorzoxazone (Paraflex) Metaxalone (Skelaxin), Cyclobenzaprine (Flexiril), Dantrolene (Dantrium), Orphenadrine (Norflex, Banflex, Myotrol).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		Risk: **"Most muscle relaxants are poorly tolerated by the elderly, leading to anticholinergic side effects, sedation, and weakness."** Anticholinergic side effects include symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. 9. Antihistamines Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril, Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripelennamine (PBZ), Dexchlorpheniramine (Polarmine). Risk: **"All nonprescription and many prescription antihistamines have a potent anticholinergic properties."** Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. When used to treat or prevent allergic reactions, antihistamines should be used in the smallest possible dose, and for the shortest period of time, and with great caution. DIAGNOSIS/DRUG COMBINATIONS WITH HIGH POTENTIAL FOR LESS SEVERE OUTCOMES 1. Diabetes Drugs: Corticosteriods such as Beclomethasone (beclovent, Vanceril), Betamethasone (Celestone), Cortisone Acetate(Cortone Acetate), Dexamethasone (Decadron, Dexone), Hydrocortisone (Cortef), Methyl prednisone (medrol), Prednisolone (many brands), Prednisone (many brands). Risk: **"May worsen diabetic control, if recently started."**

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		If Recently Started: The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should pay close attention to obtaining a rationale for its use during that time. The surveyor should be responsible for indepth investigation to determine when the drug was actually started. It should be noted that rapid withdrawal of these medicines in a steroid-dependent person can cause serious side effects. 2. Active or recurrent gastritis, peptic ulcer disease or gastroesophageal reflux disease. Drugs: Aspirin in excess of 325 mg. per day. Risk: **"May exacerbate ulcer disease, gastritis, and gastroesophageal reflux disease (GERD)."** (Note: The panelists did not believe that enteric coated aspirin would be beneficial since aspirin exacerbates these conditions primarily through its systemic effects rather than its local effects.) Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence. Drugs: Potassium supplements such as Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K or Ten K. This includes liquid oral dosage forms which, if used, should be administered after meals with an optimal amount of water or fruit juice (depending on the resident's fluid restrictions) to decrease the potential of gastric distress or bad taste as much as possible. Risk: **"May cause gastric irritation with symptoms similar to ulcer disease."** Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence. Exception: Use of these medications to treat low potassium levels until they return to normal range if determined by the prescriber that use of fresh fruits and vegetables or other dietary supplementation is not adequate or possible.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		3. Seizures or Epilepsy Drugs: Clozapine (Clozaril), Chlorpromazine (Thorazine), Thioridazine (Mellaril), Chlorpropthixene (Taractan), Metoclopramide (Reglan), Fluphenazine (Prolixin, Permitil), Perphenazine (Trilafon), Mesoridazine (Serentil), Prochlorperazine (Compazine), Promazine (Sparine), Trifluoperazine (Stelazine), Triflupromazine (Vesprin), Haloperidol (Haldol), Loxapine (Loxitane), Molindone (Moban), Olanzapine (Zyprexa), Pimozide (Orap), Risperidone (Risperdal), Thiothixene (Navane), Quetiapine (Seroquel). Risk: **"May lower seizure threshold."** Potential Side Effect: Increased risk of seizure activity. Exception: Use of these drugs within the already established HCFA guidelines (483.25(l)) for a 72 hour period or less, when treating acute psychosis, such that the individual is a danger to self or others. 4. Benign Prostatic Hypertrophy (BPH) Drugs: Narcotic drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphene (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.). Risk: **"Anticholinergic drugs may impair micturition and cause obstruction in men with BPH."** Potential Side Effects: Urinary retention, urinary incontinence, reflux, pyelonephritis, nephritis, low grade temperature, low back pain. Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		Drugs: Flavoxate (Urispas), Oxybutynin (Ditropan), Bethanechol (Urecholine, Duvoid). Risk: **"Bladder relaxants may cause obstruction in persons with BPH."** Potential Side Effects: Urinary retention, incontinence, hesitancy, reflux, hydronephrosis. 5. Constipation Drugs: **Anticholinergic antihistamines** such as Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril & Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripeleennamine (PBZ), Dexchlorpheniramine (Polaramine). Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. **Anti-Parkinson medications** such as Benztropine (Cogentin), Trihexyphenidyl (Artane), Procyclidine (Kemadren), Biperiden (Akineton). **GI Antispasmodics** such as Dicyclomine (Bentyl), Hyoscyamine (Levsin & Levsinex), Propantheline (Pro-Banthine), Belladonna Alkaloids (Donnatal), Clidinium containing products such as Librax. Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. **Anticholinergic antidepressant** drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

GUIDANCE TO SURVEYORS - LONG TERM CARE FACILITIES

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		**Narcotic Drugs** such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphen (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.). Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. 6. Insomnia Drugs: o Decongestants such as Phenylephrine (Duo-Medihaler), Phenylpropanolamine (Genex), Pseudoephedrine (Novafed, Sudafed, Triaminic AM, Efidac/24); o Theophylline (Elixophyllin Bronkodyl, Theo-Dur, Slo-Bid); o Desipramine (Pertofrane, Norpramin); o Selective Serotonin Reuptake Inhibitors such as Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft); o Methylphenidate (Ritalin); o Monamine Oxidase Inhibitors (MAOIs) such as Phenelzine (Nardil), Tranylcypromine (Parnate); and o Beta Agonists such as Isoproterenol (Isuprel), Albuterol (Proventil), Bitolterol (Tornalate), Terbutaline (Brethine). Risk: "**May cause or worsen insomnia."** (The surveyor should consider that insomnia is often a symptom of untreated depression and Chronic Obstructive Pulmonary Disease (COPD.))

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F430	these reports must be acted upon.	Guidelines: §483.60(c)(2) The director of nursing and the attending physicians are not required to agree with the pharmacist=s report, nor are they required to provide a rationale for their "acceptance" or "rejection" of the report. They must, however, act upon the report. This may be accomplished by indicating acceptance or rejection of the report and signing their names. The facility is encouraged to provide the medical director with a copy of drug regimen review reports and to involve the medical director in reports that have not been acted upon.
F431	(d) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.	Guidelines: §483.60(d) This section imposes currently accepted labeling requirements on facilities, even though the pharmacies will be immediately responsible for accomplishing the task. The critical elements of the drug label in a long-term care facility are the name of the drug and its strength. The names of the resident and the physician do not have to be on the label of the package, but they must be identified with the package in such a manner as to assure that the drug is administered to the right patient. All drugs approved by the Food and Drug Administration must have expiration dates on the manufacturer's container. "When applicable" means that expiration dates must be on the labels of drugs used in long term care facilities unless State law stipulates otherwise.
F432	(e) Storage of drugs and biologicals. (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.	Guidelines: §483.60(e) Compartments in the context of these regulations include but are not limited to drawers, cabinets, rooms, refrigerators, carts, and boxes. The provisions for authorized personnel to have access to keys must be determined by the facility management in accordance with Federal, State, and local laws and facility practices. "Separately locked" means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs. Probes: §483.60(e) Are all drugs and biologicals stored properly, locked and at proper temperature?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F432 Cont.	(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F441	§483.65 Infection control. The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection. (a) Infection control program. The facility must establish an infection control program under which it-- (1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections.	Intent: §483.65(a) The intent of this regulation is to assure that the facility has an infection control program which is effective for investigating, controlling, and preventing infections. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2. Guidelines: §483.65(a) The facility's infection control program must have a system to monitor and investigate causes of infection (nosocomial and community acquired) and manner of spread. A facility should, for example, maintain a separate record on infection that identifies each resident with an infection, states the date of infection, the causative agent, the origin or site of infection, and describes what cautionary measures were taken to prevent the spread of the infection within the facility. The system must enable the facility to analyze clusters, changes in prevalent organisms, or increases in the rate of infection in a timely manner. Surveillance data should be routinely reviewed and recommendations made for the prevention and control of additional cases. The written infection control program should be periodically reviewed by the facility and revised as indicated. Current standards for infection control program address the following. The following are not regulatory requirements but provide guidance for evaluating the facility's program. o Definition of nosocomial/facility acquired infections and communicable diseases. o Risk assessment of occurrence of communicable diseases for both residents and staff that is reviewed annually, or more frequently if indicated. o Methods for identifying, documenting and investigating nosocomial infections and communicable diseases. The infection control program should be able to identify new infections quickly, paying particular attention to residents at high risk of infection of infection (e.g. residents who are immobilized, have invasive devices or procedures, have pressure sores, have been recently discharged from a hospital to the long term care facility, have MI or MR, have decreased mental status, are nutritionally compromised or have altered immune systems). o Early detection of residents who have signs and symptoms of TB and a referral protocol to a facility where TB can be evaluated and managed appropriately. o Measures for prevention of infections, especially those associated with intravascular therapy, indwelling urinary catheters, tracheostomy care, stoma care, respiratory care, immunosuppression, pressures sores, bladder and bowel incontinence and any other factors which compromise a resident's resistance to infections.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F441 Cont.		o Measures for the prevention of communicable disease outbreaks, including tuberculosis, flu, hepatitis, scabies, MRSA. o Procedures to inform and involve a local or State epidemiologist, as required by the State for non-sporadic, facility-wide infections that are difficult to control. o Isolation procedures and requirements for infected and at risk or immunosuppressed nursing home residents. o Use of and inservice education regarding standard precautions, (e.g., universal precautions/body substance isolation). o Handwashing, respiratory protection, linen handling, housekeeping, needle and hazardous waste disposal, as well as other means for limiting the spread of communicable organisms. o Authority, indications, and procedures for obtaining and acting upon microbiological cultures from residents and for isolating residents. o Proper use of disinfectants, antiseptics and germicides in accordance with the manufacturers' instructions and EPA of FDA label specifications to avoid harm to staff, residents and visitors and to ensure its effectiveness. o Orientation of all new facility personnel to the infection control program and periodic updates for all staff. o Measures for the screening of the health care workers for communicable diseases, and for the evaluation of workers exposed to residents with communicable diseases including TB and Blood Borne Pathogens. o Work restriction guidelines for an employee that is infected or ill with a communicable disease. o Measures which address prevention of infection common to nursing home residents (e.g., vaccination for influenza and pneumococcal pneumonia as appropriate) TB screening and testing. o Sanitization of tubs, whirlpools and multiple use equipment to be performed according to manufacturer's recommendations. Observe whether staff including direct care, housekeeping, kitchen staff, use gloves in accord with aseptic principles. Determine if there is consistent use of aseptic technique for dressing changes. If breaks in technique are observed, verify that the facility has a system in place for routine monitoring of staff infection control practices. Ask direct care giver staff what do they do and who do they notify when an infection is noted.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F441 Cont.		Procedures: §483.65(a) Observe sanitation of tub, shower, multiple residents' whirlpool and care equipment, as necessary. Identify all residents in the sample who are currently on antibiotic therapy and verify that these residents are reported on the facility's infection control logs/records to ensure that infections are being identified timely and that these residents are being adequately monitored for infection. Review policies related to infection control if observation, record review, or staff interview indicate a problem with infection control. Observe direct care staff routinely washing their hands according to facility written protocols. Probes: §483.65(a) o Are there unexplained and/or similar infections? For sampled residents at high risk of infection, what has staff done to reduce residents' risk of infection? o Do surveillance data show a significant increase in the rate of infection from month to month? Over several months? How is this being addressed? o What infection control policies does the facility use for persons with AIDS, TB, or hepatitis B? Do these policies conform with Occupational Safety and Health Administration's requirements for protecting employees and current accepted standards of practice recommended by Centers for Disease Control and Prevention (CDC)? Does the staff follow its own procedures? o How does the facility define and dispose of its infectious waste?
F442	(b) Preventing spread of infection. (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.	Intent: §483.65(b) The intent of this regulation is to assure that the facility isolates residents appropriately to prevent the spread of infection. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F442 Cont.		Guidelines: §483.65(b) Procedures must be followed to prevent cross-contamination, including handwashing and/or changing gloves after providing personal care, or when performing tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for handwashing must exist and be available to staff. The facility should follow the CDC's Guideline for Handwashing and Hospital Environmental Control, 1985 for handwashing. The facility should isolate infected residents only to the degree needed to isolate the infecting organism. The method used should be the least restrictive possible, while maintaining the integrity of the process. For example, the HIV virus is present in blood and other body fluids. The facility should take universal or standard blood and body fluid precautions related to HIV contamination for the following: o Blood; o Semen; o Vaginal secretions; o Cerebrospinal fluid; o Synovial fluid; o Pleural fluid; o Peritoneal fluid; o Pericardial fluid; o Amniotic fluid; and/or o Fluids with visible blood. Residents, visitors and employees should be protected from these fluids. Although the resident infected with HIV should not be isolated routinely, the resident should be isolated if he/she is in the communicable stages of an opportunistic infection, his/her body fluids cannot be contained or he/she has very poor hygiene and the likelihood of spillage is high. NOTE: TB isolation rooms are not needed if the facility does not provide care to active TB patients/residents. "Universal precautions" or "Standard blood and body fluid precautions" is an approach to infection control where all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. Probes: §483.65(b) o For isolated residents, does the facility need to segregate them to control the infectious agent? o For residents who have been isolated appropriately, does staff use correct procedures consistently? For example, if isolation procedures require wearing gowns, do all staff put on and dispose of the gown in a way that lessens the spread of infection?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F442 Cont.		o How does the facility control the spread of infection by persons who visit infectious residents? Is there a written protocol? o Do persons with a communicable disease or infected skin lesions provide care to residents? o Have any residents developed a communicable disease as defined by State law while in the facility? If so, have appropriate barrier or isolation precautions been followed to control further spread of infection? Procedures: §483.65(b)(1) Verify that all residents who require isolation as determined by the infection control program are isolated. Observe residents that have been isolated. Determine what level of isolation they are required to have. Evaluate isolation procedures utilized by staff members. Determine if the facility has isolated the resident in the least restrictive environment possible.
F443	(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.	Intent: §483.65(b)(2) The intent of this regulation is to prevent the spread of communicable diseases from employees to residents when the employee has a communicable disease or an infected skin lesion. State law defines communicable diseases for purposes of defining facility policies. Skin lesions should be considered infected if they have purulent drainage, or are res, hot, indurated without purulent drainage. Procedures: §483.65(b)(2) Determine if the facility prohibits employees with diseases communicable through direct contact or infected skin lesions from having direct contact with residents. To make this determination, observe residents' condition and treatments provided, interview facility staff, and review relevant facility policies and procedures for preventing the spread of infection.
F444	(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.	Intent: §483.65(b)(3) The intent of this regulation is to assure that staff use appropriate handwashing techniques to prevent the spread of infection from one resident to another. Guidelines: §483.65(b)(3) Procedures must be followed to prevent cross-contamination, including handwashing or changing gloves after providing personal care, or when performing tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for handwashing must exist and be readily available to staff. The facility should follow the CDC's Guideline for Handwashing and Hospital Environmental Control, 1985 for handwashing.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F444 Cont.		Procedures: §483.65(b)(3) Verify that the facility has policy that requires staff to wash their hands after each direct resident contact when indicated. Observe hand washing by staff after direct contact with residents. It is important for the surveyor to begin a thorough investigation of the facility's infection control program when poor resident outcomes and poor practices are observed. Probes: §483.65(b)(3) o Does the facility have a written protocol describing handwashing practices and is it consistent with the latest published standards? o Do staff follow the facility policy and protocol for handwashing?
F445	(c) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.	Intent: §483.65(c) The intent of this regulation is to prevent the spread of infection through linens. Guidelines: §483.65(c) Soiled linens should be handled to contain and to minimize aerosolization and exposure to any waste products. Soiled linen storage areas should be well ventilated and maintained under a relative negative air pressure. The laundry should be designed to eliminate crossing of soiled and clean linen. Probes: §483.65(c) o Do staff handle linens on the resident care floors and in the laundry area to prevent the spread of infection? o Do staff follow the facility's protocols for handling linens? o Are linens processed, transported, stored, and handled properly?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F454	§483.70 Physical environment. The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.	Guidelines: §483.70(a) A waiver of specific provisions of the Life Safety Code is reviewed each time a facility is certified. The State fire authority will determine if the waiver continues to be justified, in that compliance with the requirement would result in an unreasonable hardship upon the facility and does not adversely affect the health and safety of residents or personnel. The State fire authority will forward its findings and recommendation as soon as possible to the State survey agency which will forward it to the HCFA RO for a decision on granting a waiver. Procedures: §483.70(a) The survey for safety from fire is normally conducted by the designated State fire authority. The State agency must establish a procedure for the State fire authority to notify them whether the facility is or is not in compliance with the requirement. If the survey team observes fire hazards or possible deficiencies in life safety from fire, they must notify the designated State fire authority or the RO.
	(a) Life safety from fire. Except as provided in paragraph (a)(1) or (a)(3) of this section, the facility must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference). Incorporation of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51 that govern the use of incorporations by reference. The Code is available for inspection at the Office of the Federal Information Center, Room 8301, 1110 L Street N.W., Washington, D.C. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02200. If any changes in this code are also to	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	be incorporated by reference, a notice to that effect will be published in the Federal Register. (1) A facility is considered to be in compliance with this requirement as long as the facility-- (i) On November 26, 1982, complied with or without waivers, with the requirements of the 1967 or 1973 editions of the Life Safety Code and continues to remain in compliance with those editions of the Code; or (ii) On May 9, 1988, complied, with or without waivers, with the 1981 edition of the Life Safety Code and continues to remain in compliance with that edition of the Code. (2) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of residents or personnel. (3) The provisions of the Life Safety Code do not apply in a State where HCFA finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.	
F455	(b) Emergency power. (1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.	Guidelines: §483.70(b)(1) "Emergency electrical power system" includes, at a minimum, battery-operated lighting for all entrances and exits, fire detection and alarm systems, and extinguishing systems. An "exit" is defined as a means of egress which is lighted and has three components: an exit access (corridor leading to the exit), an exit (a door), and an exit discharge (door to the street or public way). We define an entrance as any door through which people enter the facility. Furthermore, when an entrance also serves as an exit, its components (exit access, exit, and exit discharge) must be lighted. A waiver of lighting required for both exits and entrances is not permitted. Procedures: §483.70(b)(1) Review results of inspections by the designated State fire safety authority that the emergency power system has been tested periodically and is functioning in accordance with the Life Safety Code. Check placement of lighting system to ensure proper coverage of the listed areas. Test all batteries to ensure they work.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F455 Cont.	(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises	Probes: §483.70(b)(1) Is emergency electrical service adequate? Additional guidance is available in the National Fire Protection Association's Life Safety Code 99 and 101 (NFPA 99 and NFPA 101), 12-5.1.3 which is surveyed in tags K105 and K106 of the Life Safety code survey. Guidelines: §483.70(b)(2) "Life support systems" is defined as one or more Electro-mechanical device(s) necessary to sustain life, without which the resident will have a liklihood of dying (e.g., ventilators suction machines if necessary to maintain an open airway). The determination of whether a piece of equipment is life support is a medical determination dependent upon the condition of the individual residents of the facility e.g. suction machine maybe required "life support equipment" in a facility, depending on the needs of its residents). Procedures: §483.70(b)(2) If life support systems are used determine if there is a working emergency generator at the facility, A generator is not required if a facility does not use life support systems. Check that the emergency generator starts and transfers power under load conditions within 10 seconds after interruption of normal power. Where residents are on life support equipment, do not test transfer switches by shutting off the power unless there is an uninterupible power supply available. Probes §483.70(b)(2) Is there a working generator if the facility is using life support systems?
Refer to F246	(c) Space and equipment The facility must – (1) Provide sufficient space and equipment in ding, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and	Intent §483.70 (c)(1) The intent of this regulation is to ensure that dining, health services, recreation, activities and programs areas are large enough to comfortably accommodate the needs of the residents who usually occupy this space. Therefore, if the survey team determines that there is a negative effect on a resident, refer to F246. Dining, health services, recreation, and program areas should be large enough to comfortably accommodate the persons who usually occupy that space, including the wheelchairs, walkers, and other ambulating aids used by the many residents who require more than standard movement spaces. "Sufficient space" means the resident can access the area, it is not functionally off-limits, and the resident's functioning is not restricted once access to the space is gained.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F456 Refer to F2523	(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition. (d) Resident rooms. Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.	Program areas where resident groups engage in activities focused on manipulative skills and hand-eye coordination should have sufficient space for storage of their supplies and "works in progress." Program areas where residents receive physical therapy should have sufficient space and equipment to meet the needs of the resident's therapy requirement. Recreation/activities area means any area where residents can participate in those activities identified in their plan of care. Procedures: §483.70(c)(1) In the use of space, consider if available space allows residents to pursue activities and receive health services and programs as identified in their care plan. If the team determines that there is inadequate space and equipment to enable staff to provide residents with needed services, refer to F246. Probes: §483.70(c)(2) Is essential equipment (e.g., boiler room equipment, nursing unit/medication room refrigerators, kitchen refrigerator/freezer and laundry equipment) in safe operating condition? Is equipment maintained according to manufacturers recommendations. Guidelines: §483.70(d) If the survey team determines that the facility does not provide rooms designed and equipped for adequate care, comfort and privacy, refer to F252.
F457	(1) Bedrooms must-- (i) Accommodate no more than four residents;	Guidelines: §483.70(d)(1)(i) See §483.70(d)(3) regarding variations. Probes: §483.70(d)(1)(i) Unless a variation has been applied for and approved under §483.70(d)(3), do the residents' bedrooms accommodate no more than four residents?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F458	(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;	Guidelines: §483.70(d)(1)(ii) See §483.70(d)(3) regarding variations. The measurement of the square footage should be based upon the useable living space of the room. Therefore, the minimum square footage in resident rooms should be measured based upon the floor's measurements exclusive of toilets and bath areas, closets, lockers, wardrobes, alcoves, or vestibules. However, if the height of the alcoves or vestibules reasonably provides useful living area, then the corresponding floor area may be included in the calculation. The space occupied by movable wardrobes should be excluded from the useable square footage in a room unless it is an item of the resident's own choice and it is in addition to the individual closet space in the resident's room. Non-permanent items of the resident's own choice should have no effect in the calculation of useable living space. Protrusions such as columns, radiators, ventilation systems for heating and/or cooling should be ignored in computing the useable square footage of the room if the area involved is minimal (e.g., a baseboard heating or air conditioning system or ductwork that does not protrude more than 6 to 8 inches from the wall, or a column that is not more than 6 to 8 inches on each side) and does not have an adverse effect on the resident's health and safety or does not impede the ability of any resident in that room to attain his or her highest practicable well-being. If these protrusions are not minimal they would be deducted from useable square footage computed in determining compliance with this requirement. The swing or arc of any door which opens directly into the resident's room should not be excluded from the calculations of useable square footage in a room. Procedures: §483.70(d)(1)(ii) The facility layout may give square footage measurements. Carry a tape measure and take measurements if the room appears small. Probes: §483.70(d)(1)(ii) Unless a variation has been applied for and approved under §483.70(d)(3), are there at least 80 square feet per resident in multiple resident rooms and at least 100 square feet for single resident rooms?
F459	(iii) Have direct access to an exit corridor;	Guidelines: §483.70(d)(1)(iii) There is no authority under current regulations to approve a variation to this requirement. Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101), 12-2.5.1, which is tag K41 of the Life Safety Code survey

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F460	(iv) Be designed or equipped to assure full visual privacy for each resident; (v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;	Guidelines: §483.70(d)(1)(iv) "Full visual privacy" means that residents have a means of completely withdrawing from public view while occupying their bed (e.g., curtain, moveable screens, private room). The guidelines do not intend to limit the provisions of privacy to solely one or more curtains, movable screens or a private room. Facility operators are free to use other means to provide full visual privacy, with those means varying according to the needs and requests of residents. However, the requirement explicitly states that bedrooms must "be designed or equipped to assure full visual privacy for each resident." For example, a resident with a bed by the window cannot be required to remain out of his or her room while his/her roommate is having a dressing change. Room design or equipment must provide privacy. Surveyors will assess whether the means the facility is using to assure full visual privacy meets this requirement without negatively affecting any other resident rights. Procedures: §483.70(d)(1(iv) There are no provisions for physician statements to be used as a basis for variation of the requirements for full visual privacy. Probes: §483.70(d)(1)(iv) Observe whether each resident selected for a comprehensive or focused review has a means to achieve full visual privacy. Guidelines: §483.70(d)(1)(v) The term "initially certified" is defined as all newly certified nursing facilities (NFs) or SNFs as well as NFs and SNFs after March 31, 1992, which re-enter the Medicare or Medicaid programs, whether they voluntarily or involuntarily left the program. It is not necessary for the bed to be accessible from both sides when the privacy curtain in pulled. Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101), 31-1.4.1, 31-4.5, which is tag K74 of the Life Safety Code survey.
F461	(vi) Have at least one window to the outside; and	Guidelines: §483.70(d)(1)(vi) A facility with resident room windows, as defined by section 13-3.8.1 of the 1985 edition of the Life Safety Code, that open to an atrium in accordance with Life Safety Code 6-2.2.3.5 can meet this requirement for a window to the outside.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F461 Cont.	(vii) Have a floor at or above grade level.	In addition to conforming with the Life Safety Code, this requirement was included to assist the resident's orientation to day and night, weather, and general awareness of space outside the facility. The facility is required to provide for a "safe, clean, comfortable and homelike environment" by deemphasizing the institutional character of the setting, to the extent possible. Windows are an important aspect in assuring the homelike environment of a facility. Probes: §483.70(d)(1)(vi) Is there at least one window to the outside? Guidelines: §483.70(d)(1)(vii) "At or above grade level" is defined as a room in which the floor is at or above ground level. Probes: §483.70(d)(1)(vii) Are the bedrooms at or above ground level? Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101), 12-2.5.1, 12-2.5.7, which is tag K41 of the Life Safety Code survey.
Refer to F246	(2) The facility must provide each resident with-- (i) A separate bed of proper size and height for the convenience of the resident; (ii) A clean, comfortable mattress; (iii) Bedding appropriate to the weather and climate; and	Procedures: §483.70(d)(2)(i)(ii)(iii) If the survey team determines that these requirements are not met, refer to F246. Probes: §483.70(d)(2)(i), (ii) and (iii) Are mattresses clean and comfortable? Is bedding appropriate to weather and climate?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Refer to F246	(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.	Guidelines: §483.70(d)(2)(iv) "Functional furniture appropriate to the residents' needs" means that the furniture in each resident's room contributes to the resident attaining or maintaining his or her highest practicable level of independence and well-being. In general, furnishings include a place to put clothing away in an organized manner that will let it remain clean, free of wrinkles, and accessible to the resident while protecting it from casual access by others, a place to put personal effects such as pictures and a bedside clock, and furniture suitable for the comfort of the resident and visitors (e.g., a chair). There may be instances in which individual residents determine that certain items are not necessary or will impede their ability to maintain or attain their highest practicable well-being (e.g., Both the resident and spouse use wheelchairs. They visit more easily without another chair in the room.) In this case, the resident's wishes should determine the furniture needs. "Shelves accessible to the resident" means that the resident, if able, or a staff person at the direction of the resident, can get to their clothes whenever they choose. Probes: §483.70(d)(2)(iv) Functional furniture Is there functional furniture, appropriate to residents' needs? Closet space Is there individual closet space with accessible clothes racks and shelves?
	(3) HCFA, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1)(i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations-- (i) Are in accordance with the special needs of the residents; and	Guidelines: §483.70(d)(3) A variation must be in accordance with the special needs of the residents and must not adversely affect the health or safety of residents. Facility hardship is not part of the basis for granting a variation. Since the special needs of residents may change periodically, or different residents may be transferred into a room that has been granted a variation, variations must be reviewed and considered for renewal whenever the facility is certified. If the needs of the residents within the room have not changed since the last annual inspection, the variance should continue if the facility so desires. Guidelines: §483.70(d)(1)(i): As residents are transferred or discharged from rooms with more than four residents, beds should be removed from the variance until the number of residents occupying the room does not exceed four.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(ii) Will not adversely affect residents' health and safety.	
F462	(e) Toilet facilities. Each resident room must be equipped with or located near toilet facilities.	Guidelines: §483.70(e) "Toilet facilities" is defined as a space that contains a lavatory and a toilet. If the resident's room is not equipped with an adjoining toilet facility, then "located near" means residents who are independent in the use of a toilet, including chairbound residents, can routinely use a toilet in the unit. Probes: §483.70(e) Are resident rooms equipped with or located near toilet and bathing facilities?
F463	(f) Resident call system. The nurses' station must be equipped to receive resident calls through a communication system from-- (1) Resident rooms; and (2) Toilet and bathing facilities.	Intent: §483.70(f) The intent of this requirement is that residents, when in their rooms and toilet and bathing areas, have a means of directly contacting staff at the nurse's station. This communication may be through audible or visual signals and may include "wireless systems". Guidelines: §483.70(f) This requirement is met only if all portions of the system are functioning (e.g., system is not turned off at the nurses' station, the volume too low to be heard, the light above a room or rooms is not working). Probes: §483.70(f) Is there a functioning communication system from rooms, toilets and bathing facilities?
F464	(g) Dining and resident activities. The facility must provide one or more rooms designated for resident dining and activities.	Guidelines: §483.70(g)(1) "Well lighted" is defined as levels of illumination that are suitable to tasks performed by a resident. Probes: §483.70(g)(1) Are there adequate and comfortable lighting levels? Are illumination levels appropriate to tasks with little glare? Does lighting support maintenance of independent functioning and task performance?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F464 Cont.	These rooms must-- (1) Be well lighted; (2) Be well ventilated, with nonsmoking areas identified;	Guidelines: §483.70(g)(2) "Well ventilated" is defined as good air circulation, avoidance of drafts at floor level, and adequate smoke exhaust removal. "Nonsmoking areas identified" is defined as signs posted in accordance with State law regulating indoor smoking policy and facility policy. Probes: §483.70(g)(2) How well is the space ventilated? Is there good air movement? Are temperature, humidity, and odor levels all accepted? Are non-smoking areas identified?
F465	(3) Be adequately furnished; and (4) Have sufficient space to accommodate all activities. (h) Other environmental conditions. The facility must provide a safe, functional, sanitary, and comfortable environment for residents, staff and the public.	Guidelines: §483.70(g)(3) An "adequately furnished" dining area accommodates different residents' physical and social needs. An adequately furnished organized activities area accommodates the specific activities offered by the facility. Probes: §483.70(g)(3) How adequate are furnishings? Are furnishings structurally sound and functional (e.g., chairs of varying sizes to meet varying needs of residents, wheelchairs can fit under the dining room table)? Guidelines: §483.70(g)(4) "Sufficient space to accommodate all activities" means that the space available is adaptable to a variety of uses and residents' needs. Probes: §483.70(g)(4) How sufficient is space in dining, health services, recreation and program areas to accommodate all activities? Are spaces adaptable for all intended uses? Is resident access to space limited? Do residents and staff have maximum flexibility in arranging furniture to accommodate residents who use walkers, wheelchairs, and other mobility aids? Is there resident crowding?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	The facility must--	
F466	(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;	Guidelines: §483.70(h)(1) The facility should have a written protocol which defines the source of water provisions for storing the water, both potable and non-potable, a method for distributing water, and a method for estimating the volume of water required. Procedures: §483.70(h)(1) During the entrance conference, ask the administrator the facility's procedure to ensure water availability.
F467	(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;	Probes: §483.70(h)(2) How well is the space ventilated? Is there good air movement? Are temperature, humidity, and odor levels all acceptable?
F468	(3) Equip corridors with firmly secured handrails on each side; and	Guidelines: §483.70(h)(3) "Secured handrails" means handrails that are firmly affixed to the wall. Probes: §483.70(h)(3) Are handrails secure?
F469	(4) Maintain an effective pest control program so that the facility is free of pests and rodents.	Guidelines: §483.70(h)(4) An "effective pest control program" is defined as measures to eradicate and contain common household pests (e.g., roaches, ants, mosquitoes, flies, mice, and rats). Procedures: §483.70(h)(4) As part of the overall review of the facility, look for signs of vermin. Evidence of pest infestation in a particular space is an indicator of noncompliance. Probes: §483.70(h)(4) Is area pest free?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F490	§483.75 Administration. A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.	Procedures: §483.75 If there is a deficiency in §483.13, Resident behavior and facility practices; §483.15, Quality of life; or §483.25, Quality of care, which has the scope and/or severity to be defined as substandard quality of care, fully review for compliance all the tags within this section (§483.75).
F491	(a) Licensure. A facility must be licensed under applicable State and local law.	Guidelines: §483.75(a) Applicable licenses, permits and approvals must be available to you for inspection upon request. Procedures: §483.75(a) If there are problems with care provided or supervised by licensed personnel, verify applicable licenses, permits and approvals.
F492	(b) Compliance with Federal, State, and local laws and professional standards. The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.	Intent: §483.75(b) The intent of this regulation is to ensure that a facility is in compliance with Federal, State, and local laws, regulations, and codes relating to health, safety, and sanitation. Guidelines: §483.75(b) The State is responsible for making decisions about whether there are violations of State laws and regulations. Licenses, permits and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(c) Relationship to other HHS regulations. In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.	Procedures: §483.75(b) If resident/family interviews reveal possible problems with admission contracts, review these contracts for violations of requirements at §§483.10 and 483.12. As appropriate, refer problems to an ombudsman or other agencies, e.g., Office for Civil Rights. Some State or local laws are more stringent than the Federal requirement on the same issue. Failure of the facility to meet a Federal, State or local law may be cited at this tag only when the authority having jurisdiction has both made a determination of noncompliance and has taken a final adverse action as a result. Accepted professional standards and principles include the various practice acts and scope of practice regulations in each State, and current, commonly accepted health standards established by national organizations, boards and councils. If interviews with residents suggest that the facility may have required deposits from Medicare residents at admission, review the facility's admissions documents. Procedures: §483.75(c) If during the survey you identify problems relating to one or more of these requirements, which are under the purview of another Federal agency, forward the information to the RO, who will forward it to the appropriate Federal agency.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F493	(d) Governing body. (1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and (2) The governing body appoints the administrator who is-- (i) Licensed by the State where licensing is required; and (ii) Responsible for the management of the facility.	Guidelines: §483.75(d)(2)(1) The administrator must be licensed where required by the State.
	(e) Required training of nursing aides-- (1) Definitions. Licensed health professional means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker. Nurse aide means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay.	Guidelines: §483.75(e) Volunteers are not nurse aides and do not come under the nurse aide training provisions of these requirements. Unpaid students in nursing education programs who use facilities as clinical practice sites under the direct supervision of an RN are considered volunteers. Private duty nurse aides who are not employed or utilized by the facility on a contract, per diem, leased or other basis, do not come under the nurse aide training provisions.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F494	(2) General rule. A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless: (i) That individual is competent to provide nursing and nursing related services; and (ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§483.151-483.154 of this part; or (B) That individual has been deemed or determined competent as provided in §483.150(a) and (b). (3) Non-permanent employees. A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(2)(i) and (ii) of this section.	Guidelines: §483.75(e)(2 - 4) Facilities may use, as nurse aides, any individuals who have successfully completed either a nurse aide training and competency evaluation program or a competency evaluation program. However, if an individual has not completed a program at the time of employment, a facility may only use that individual as a nurse aide if the individual is in a nurse aide training and competency evaluation program (not a competency evaluation program alone) and that individual is a permanent employee in his or her first four months of employment in the facility. Facilities may not use non-permanent employees as nurse aides unless they have either completed a training and competency evaluation program, or a competency evaluation program. Probes: §483.75(e)(2 - 4) During an extended or partial extended survey: o Have all nurse aides completed a nurse aide training and competency evaluation program or a competency evaluation program? If not, are those nurse aides permanent employees enrolled in a training and competency evaluation program who have worked in the facility for 4 months or less? o Ask nurse aides where they received their training, how long the training was and how long they have worked in the facility as a nurse aide. During all surveys: o If incorrect nurse aide work performance is observed during the survey, check to see if the nurse aide received training and licensed nurse supervision to correctly carry out the task. A "permanent employee" is defined as any employee you expect to continue working on an ongoing basis. Procedures: §483.75(e)(2-4) Review competency requirements for nurse aides if you identify potential deficient care practices in quality of care, resident rights, resident behavior and facility practice or quality of life which may be related to nurse aide competency. Is there evidence that the nurse aide has successfully completed the competency evaluation program, or has the individual been grandfathered in by the State?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F495	(4) Competency. A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual-- (i) Is a full-time employee in a State-approved training and competency evaluation program; (ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or (iii) Has been deemed or determined competent as provided in §483.150(a) and (b).	If you identify deficient care practices by nurse aides who do not have evidence of having successfully completed a competency evaluation program, determine: o if the aide is currently receiving training an a State approved Nurse Aide Training Program; o if the aide is under the supervision of a licensed nurse; and o if the aide has been trained and determined to be proficient for the tasks to which he or she is assigned. See §483.152 for specific training that the aide is to receive. This training includes: o at least 16 hours of training in the following subjects before any direct contact with the resident: - communication and interpersonal skills; - infection control; - safety and emergency procedures, including the Heimlich Maneuver; - promoting resident's independence; and - respecting resident's rights. o Basic nursing skills; o Personal care skills; o Mental health and social services of residents; o Care of cognitively impaired residents; o Basic restorative services; and o Resident's rights.
F496	(5) Registry verification. Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless-- (i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F496 Cont.	(ii)The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered. (6) Multi-State registry verification. Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act the facility believes will include information on the individual. (7) Required retraining. If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.	Guidelines: §483.75(e)(7) If an individual does not wish to be retrained, the individual must establish that he or she performed nursing or nursing-related services for monetary compensation for at least one documented day (i.e., 8 consecutive hours) during the previous 24 months. The State is required to remove the individual's name from the registry if the services are not provided for monetary compensation during the 24-month period. Thus, in the absence of any evidence to the contrary, you can assume that the retraining requirement does not apply to an individual whose name appears on the registry.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F497	(8) Regular in-service education. The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must-- (i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year; (ii) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff; and (iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.	Guidelines: §483.75(e)(8) The adequacy of the in-service education program is measured not only by documentation of hours of completed in-service education, but also by demonstrated competencies of nurse aide staff in consistently applying the interventions necessary to meet residents' needs. If there has been deficient care practices identified during Phase 1 of the survey, review as appropriate training received by nurse aides in that corresponding subject area. For example, if the facility has deficiencies in infection control, review the infection control unit in the facility's inservice nurse aide training program. Each nurse aide must have no less than twelve hours of in-service education per year. Calculate the date by which a nurse aide must receive annual in-service education by the employment date rather than the calendar year. Probes: §483.75(e)(8) During an extended or partial extended survey, or during any survey in which nurse aide performance is questioned. (See §483.75(f).) o Does the facility review the performance of its nurse aides? o How has in-service education addressed areas of weakness identified in performance reviews, special resident needs, and needs of residents with cognitive impairments? o How has in-service education addressed quality of care problems including those of special care needs and resident rights?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F498	(f) Proficiency of Nurse aides. The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.	Guidelines: §483.75(f) "Competency in skills and techniques necessary to care for residents' needs" includes competencies in areas such as communication and personal skills, basic nursing skills, personal care skills, mental health and social service needs, basic restorative services and resident rights. Procedures: §483.75(f) During the Resident Review, observe nurse aides. Probes: §483.75(f) Do nurse aides show competency in skills necessary to: maintain or improve the resident's independent functioning, e.g., performing range of motion exercises, assisting the resident to transfer from the bed to a wheelchair, reinforcing appropriate developmental behavior for persons with MR, or psychotherapeutic behavior for persons with MI; observe and describe resident behavior and status and report to charge nurse; follow instructions; carry out appropriate infection control precautions and safety procedures.
F499	(g) Staff qualifications. (1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements. (2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.	Procedures: §483.75(g) If there is reason to doubt the qualifications of temporary agency personnel working in the facility, check with the appropriate registry or professional licensing board.
F500	(h) Use of outside resources. (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F500 Cont.	that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or an agreement described in paragraph (h)(2) of this section. (2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for-- (i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and (ii) The timeliness of the services.	
F501	(i) Medical director. (1) The facility must designate a physician to serve as medical director. (2) The medical director is responsible for-- (i) Implementation of resident care policies; and	Guidelines: §483.75(i) "Resident care policies" include admissions, transfers, and discharges; infection control; use of restraints; physician privileges and practices; and responsibilities of non-physician health care workers, (e.g., nursing, rehabilitation therapies, and dietary services in resident care, emergency care, and resident assessment and care planning). The medical director is also responsible for policies related to accidents and incidents; ancillary services such as laboratory, radiology, and pharmacy; use of medications; use and release of clinical information; and overall quality of care. The medical director is responsible for ensuring that these care policies are implemented.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F501 Cont.	(ii) The coordination of medical care in the facility.	The medical director's "coordination role" means that the medical director is responsible for assuring that the facility is providing appropriate care as required. This involves monitoring and ensuring implementation of resident care policies and providing oversight and supervision of physician services and the medical care of residents. It also includes having a significant role in overseeing the overall clinical care of residents to ensure to the extent possible that care is adequate. When the medical director identifies or receives a report of possible inadequate medical care, including drug irregularities, he or she is responsible for evaluating the situation and taking appropriate steps to try to correct the problem. This may include any necessary consultation with the resident and his or her physician concerning care and treatment. The medical director's coordination role also includes assuring the support of essential medical consultants as needed. A medical director whose sole function is to approve resident care policies does not meet this requirement. Probes: §483.75(i) o What does the medical director do to coordinate medical care services for residents of the facility? o How does the medical director identify and confirm problems of inadequate care?
F502	(j) Laboratory services. (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.	Intent: §483.75(j)(1) The intent of this regulation is to assure that laboratory services are accurate and timely so that the utility of laboratory testing for diagnosis, treatment, prevention or assessment is maximized. The facility is responsible for quality and timely laboratory services whether or not services are provided by the facility or an outside agency. Guidelines: §483.75(j)(1) A "laboratory service or test" is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. Services provided must be both accurate and timely. Timely means that laboratory tests are completed and results are provided to the facility (or resident's physician) within timeframes normal for appropriate intervention. All laboratories providing services for facility residents must meet applicable requirements of 42 CFR Part 493. The purpose of this requirement is to assist in assuring quality of laboratory services.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F503	(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter. (ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in Part 493 of this chapter. (iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter. (iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.	Procedures: §483.75(j)(1) Verify that laboratory services are provided to meet the needs of the residents. If a problem in quality of care leads you to suspect a problem in laboratory services, timeliness or quality, refer to the interpretive guidelines for laboratory testing found in Appendix C. Probes: §483.75(j)(1) Are problems attributable to: o An inability to order laboratory tests in a timely manner, including delays in transporting the resident to and from the source of service, if needed? o A delay of treatment due to untimely receipt of lab results? o A large lag time between an order for a test and the recording of the results that may have resulted in poor care? Intent: §483.75(j)(1)(i) - (iv) The intent of this regulation is to assure that laboratory services, bloodbank and transfusion services are obtained from an entity that meets the requirements of 42 CFR Part 493 in order to provide a standard of quality for laboratory and transfusion services. If the long term care facility does not provide laboratory services on site, there must be an agreement to obtain these services from a laboratory that meets the same requirements. Guidelines: §483.75(j)(1)(i) - (iv) If a facility provides its own laboratory services, the provisions of 42 CFR Part 493 apply. The facility must have a Clinical Laboratory Improvement Amendments (CLIA) certificate appropriate for the level of testing performed. An application for a certificate of waiver may be made if the facility performs only those tests categorized as waived under CLIA. Direct questions concerning the application of these requirements to your State laboratory consultant or the HCFA RO. Procedures: §483.75(j)(1)(i) - (iv) Determine if all laboratory services provided for the facility are provided by a laboratory that meets the requirements of 42 CFR Part 493. The surveyor should determine if the facility has an arrangement in writing to assume responsibility for (a) obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and (b) the timeliness of the services.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F503 Cont.		Probes: §483.75(j)(1)(i) - (iv) Are problems attributable to: o Lack of an arrangement to provide or obtain clinical laboratory services from a source that meets the applicable conditions for coverage of the services? o Delays in interpreting the results of laboratory tests?
	(2) The facility must--	Intent: §483.75(j)(2)(i) The intent of this regulation is to assure that only medically necessary laboratory services are ordered.
F504	(i) Provide or obtain laboratory services only when ordered by the attending physician;	Procedures: §483.75(j)(2)(i) Verify that all laboratory services received were ordered by the attending physician.
F505	(ii) Promptly notify the attending physician of the findings;	Intent: §483.75(j)(2)(ii) The intent of this regulation is to assure that the physician is notified of all lab results so that prompt, appropriate action may be taken if indicated for the resident's care. Procedures: §483.75(j)(2)(ii) If you have reason to believe that a physician(s) may not have been notified of laboratory results in a timely manner, determine if the facility has a policy/procedure for routine notification of physician and if the procedure is implemented. Probes: §483.75(j)(2)(ii) o Are any problems identified as relating to lack of prompt notification of the attending physician, contributing to delays in changing the course of treatment or care plan?
F506	(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and	Intent: §483.75(j)(2)(iii) The intent of this regulation is to assure that residents are able to get to and receive necessary laboratory testing when the testing is conducted outside of the facility. Probes: §483.75(j)(2)(iii) o Does the resident ever have to cancel lab service appointments due to difficulties with transportation?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F507	(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.	Intent: §483.75(j)(2)(iv) The intent of this regulation is to assure that the laboratory performing the tests is Medicare approved, and that test results are accurate and are available for clinical management.
F508	(k) Radiology and other diagnostic services. (1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.	Intent: §483.75(k)(1) The intent of this regulation is to assure that the resident receives quality radiologic and diagnostic services in a timely manner to meet his/her needs for diagnosis, treatment, and prevention. Probes: §483.75(k)(1) If problems are identified in radiology or other diagnostic services, are problems attributable to: o An inability to order radiological and diagnostic services in a timely manner, including delays in transporting the resident for these services? o Delays in interpreting the results of X-rays and other tests? o Lack of prompt notification, in writing, of test results to the attending physician, contributing to delays in changing care plans or the course of treatment?
F509	(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in §482.26 of this subchapter. (ii) If the facility does not provide it's own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.	
	(2) The facility must--	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F510	(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;	
F511	(ii) Promptly notify the attending physician of the findings;	
F512	(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and	
F513	(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.	
F514	(l) Clinical records. (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are-- (i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized.	Intent: §483.75(l)(1) To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care. Guidelines: §483.75(l)(1) A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment. The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F515	(2) Clinical records must be retained for-- (i) The period of time required by State law; or (ii) Five years from the date of discharge when there is no requirement in State law; or, (iii) For a minor, three years after a resident reaches legal age under State law.	In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access, and reconstruction of information must be in place. The following guideline is an example of how such a system may be set up: o There is a written policy, at the health care facility, describing the attestation policy(ies) in force at the facility. o The computer has built-in safeguards to minimize the possibility of fraud. o Each person responsible for an attestation has an individualized identifier. o The date and time is recorded from the computer's internal clock at the time of entry. o An entry is not to be changed after it has been recorded. o The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications). Procedures: §483.75(l)(1) In reviewing sampled residents' clinical records: o Is there enough record documentation for staff to conduct care programs and to revise the program, as necessary, to respond to the changing status of the resident as a result of interventions? o How is the clinical record used in managing the resident's progress in maintaining or improving functional abilities and mental and psychosocial status? Intent: §483.75(l)(3)(4) To maintain the safety and confidentiality of the resident's record. Guidelines: §483.35(l)(3) and (4) "Keep confidential" is defined as safeguarding the content of information including video, audio, or other computer stored information from unauthorized disclosure without the consent of the individual and/or the individual's surrogate or representative. If there is information considered too confidential to place in the record used by all staff, such as the family's financial assets or sensitive medical data, it may be retained in a secure place in the facility, such as a locked cabinet in the administrator's office. The record should show the location of this confidential information. Procedures: §483.75(l)(3) and (4) Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents' records.
F516	(3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;	
Refer to F164	(4) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by-- (i) Transfer to another health care institution; (ii) Law;	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(iii) Third party payment contract; or (iv) The resident.	Probes: §483.75(1)(3) and (4) o How does the facility ensure confidentiality of resident records/ o If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?
Refer to F514	(5) the clinical record must contain— (i) Sufficient information to identify the resident; (ii) A record of the resident's assessments; (iii) the plan of care and services provided; (iv)The results of any preadmission screening conducted by the State; and (v) progress notes.	
	(m) disaster and emergency preparedness.	Guidelines: §483.75(m) The facility should tailor its disaster plan to its geographic location and the types of residents it serves. "Periodic review" is a judgement made by the facility based on its unique circumstances changes in physical plant or changes external to the facility can cause a review of the disaster review plan The purpose of a staff drill" is to test the efficiency, knowledge, and response of institutional personnel in the event of an emergency. Unannounced staff drills are directed at the responsiveness of staff, and care should be taken not to disturb or excite residents. Procedures; §483.75(m) Review and disaster and emergence preparedness plan, including plans for natural or man made disasters Probes: §483.75(m) Ask two staff persons separately (e.g., nurse aide, housekeeper, maintenance person) and the charge nurse: o If the fire alarm goes off, what do you do? o If you discover that a resident missing, what do you do?
F517	(1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.	
F518	(2) The facilities must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff,.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F518 Cont.	and carry out unannounced staff drills using those procedures	o What would you do if you discovered a fire in a resident's room? Where are fire alarms and fire extinguisher(s) located on this unit? o How do you use the fire extinguisher? Note: Also, construct probes relevant to a geographically specific natural emergencies (e.g., for areas prone to hurricanes, tornadoes, earthquakes, or floods, each of which may require a different response). Are the answers to these questions correct (staff answers predict competency in assuring resident safety)?
F519	(n) Transfer agreement (1) In accordance with section 1861(1) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that— (i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate, as determined by the attending physician; and (ii) Medical and other information needed for care and treatment of residents, and , when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions	

<table>
<tr><th colspan="3">GUIDANCE TO SURVEYORS – LONG TERM CARE FACILITIES</th></tr>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td>F519 Cont.</td><td>(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.</td><td></td></tr>
<tr><td></td><td>(o) Quality assessment and assurance.</td><td rowspan="3">Intent: §483.75(o)
The intent of this regulation is to ensure the facility has an established quality assurance committee in the facility which identifies and addresses quality issues, and implements corrective action plans as necessary.

Guidelines: §483.75(o)
The quality assessment and assurance committee is responsible for identifying issues that necessitate action of the committee, such as issues which negatively affect quality of care ands services provided to residents. In addition, the committee develops and implements plans of action to correct identified quality deficiencies. The medical director may be the designated physician who serves on this committee pursuant to §483.75(o)(1)(ii).

Procedures: §483.75(o)
This requirement is reviewed only after completion of phase 2 sampling. There are two phases to the quality assurance review. During phase 1 for all facilities:
o The survey team should review how the quality assurance committee functions. Determine through interviews with administrative staff and Quality Assessment and Assurance Committee members if the facility has a Quality Assurance Committee which meets the requirements in §483.75(o).
o Determine if the committee has a formal method to identify issues in the facility which require quality assessment and assurance activities. The facility should also have a method to respond to identified issues and a means to evaluate the response to these issues.

Phase 2 of the review should be conducted if the survey team has identified quality issues. During Phase 2:
o Verify, through interviews with committee members and, as necessary, direct care staff that the committee has established a protocol or method for addressing specific quality problems in the facility that the facility believes have now been resolved.</td></tr>
<tr><td>F520</td><td>(1) A facility must maintain a quality assessment and assurance committee consisting of--

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee--</td></tr>
<tr><td>F521</td><td>(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and</td></tr>
</table>

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F521 Cont.	(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies. (3) A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section. (4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.	Do not review committee records identifying details of the specific quality deficiencies. Surveyors should not focus on if the quality assurance committee has identified and addressed deficiencies which the survey team identifies. Concentrate on verifying that the facility has a quality assurance committee which addresses quality concerns and that staff know how to access that process. Probes: §483.75(o) When conducting interviews: o How are facility policies and clinical policies revised based on quality assurance findings? See Task 5F for detailed information concerning survey procedures.
F522	(p) Disclosure of ownership. (1) The facility must comply with the disclosure requirements of §§420.206 and 455.104 of this chapter. (2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in-- (i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter; (ii) The officers, directors, agents, or managing employees; (iii) The corporation, association, or other company responsible for the management of the facility; or	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F522 Cont.	(iv) The facility's administrator or director of nursing. (3) The notice specified in the paragraph (p)(2) of this section must include the identity of each new individual or company.	